ACIDEX MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

BOOTS MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

PL 04917/0113
PL 04917/0114

UKPAR

TABLE OF CONTENTS

Lay Summary ........................................ Page 2
Scientific discussion .......................... Page 3
Steps taken for assessment ................. Page 11
Steps taken after authorisation – summary Page 12
Summary of Product Characteristics .... Page 13
Patient Information Leaflet ................. Page 19
Labelling ........................................... Page 43
ACIDEEX MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

BOOTS MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

LAY SUMMARY

On 24th February 2012, the MHRA granted Pinewood Laboratories Limited Marketing Authorisations (licences) for Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed/peppermint flavour).

Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension belong to a group of products called reflux suppressants. Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion.

Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension outweigh the risks; hence these Marketing Authorisations have been granted.
ACIDEX MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

BOOTS MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction ........................................ Page 4
Pharmaceutical assessment ...................... Page 5
Non-clinical assessment .......................... Page 8
Clinical assessment (including statistical assessment) ...................................... Page 9
Overall conclusions and risk benefit assessment ............................................ Page 10
INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted Marketing Authorisations for the medicinal product Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed/peppermint flavour) (PL 04917/0113-4) to Pinewood Laboratories Limited on 24th February 2012.

These products have a general sales licence (GSL) and are indicated for the alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

These applications for Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets is submitted as an abridged application according to Article 10.3 of Directive 2001/83/EC, as amended, claiming to be a hybrid product to Gaviscon Liquid, originally approved in the UK to Reckitt & Colman on 14th April 1977 (PL 00044/0058).

When the product is taken after a meal, sodium alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft. This suppresses reflux.

The pharmacovigilance system as described by the applicant fulfils the requirements. It also provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring.

A satisfactory justification for the absence of a Risk Management Plan (RMP) has been provided.
PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

**Sodium Alginate**
INN: Sodium alginate
Structure:

Physical form: A white to pale yellowish-brown powder.
Solubility: Soluble in water, practically insoluble in alcohol.

Molecular formula: \((\text{NaC}_6\text{H}_7\text{O}_6)n\)
Molecular weight: 216

**Sodium Bicarbonate (sodium hydrogen carbonate)**
INN: Sodium hydrogen carbonate
Structure:

Physical form: White crystalline powder
Solubility: Soluble in water and very slightly soluble in alcohol

Molecular formula: NaHCO₃
Molecular weight: 84.0

**Calcium Carbonate**
INN: Calcium carbonate
Structure:

Physical form: White or almost white powder
Solubility: Largely insoluble in water
Molecular formula: \( \text{CaCO}_3 \)
Molecular weight: 100.09

The sources of sodium alginate, sodium bicarbonate and calcium carbonate comply with the relevant European Pharmacopoeia monographs for sodium alginate, sodium bicarbonate and calcium carbonate.

Synthesis of the active substances from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant Certificates of Analysis.

Appropriate specifications have been provided for the active substances. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Appropriate proof-of-structure data have been supplied for the active substances. Satisfactory Certificates of Analysis have been provided for all working standards. Batch analysis data are provided and comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines.

Confirmation was provided that the active substances will be tested before each production campaign. A suitable re-test period has been provided and is approved.

**DRUG PRODUCT**

**Other ingredients**

Other ingredients consist of pharmaceutical excipients carbomer, sodium hydroxide, saccharin sodium, ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate, isopropyl alcohol and purified water.

PL 04917/0113 has the additional excipient, aniseed oil.

PL 04917/0114 has the additional excipient, peppermint oil.

All excipients comply with their relevant European Pharmacopoeia monographs. None of the excipients used contain material of animal or human origin. No genetically modified organisms (GMO) have been used in the preparation of these products.

**Pharmaceutical Development**

The objective of the development programme was to produce oral suspensions containing sodium alginate, sodium bicarbonate and calcium carbonate that could be considered hybrid products of Gaviscon Liquid. The difference between the products being that the produced product would be twice as concentrated (twice as much sodium alginate) as Gaviscon Liquid therefore a smaller dosage volume dosage would be required.

The applicant has provided suitable product development information. Valid justifications for the use and amounts of each excipient have been provided.
Manufacturing Process
Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results. Satisfactory process validation data on batches have been provided.

Finished product specification
The finished product specifications are satisfactory. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specifications. Certificates of Analysis for any working standards used have been provided.

Container-Closure System
The products are packaged in Type III amber glass bottles with white polypropylene (PP) caps that have a low-density polyethylene (LDPE) liner. Pack sizes are 150ml, 200ml, 250ml and 500ml. Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary product packaging complies with EU legislation.

Stability of the product
Stability studies were performed on batches of the finished products in the packaging proposed for marketing and in accordance with current guidelines. These data support a shelf-life of 24 months for an unopened product. The shelf-life after opening the product is 3 months.

The storage instructions are ‘Do not store above 25°C. Do not refrigerate or freeze.’ This is satisfactory.

Summary of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and Labelling
The SmPCs, PIL and labelling are pharmaceutically acceptable.

User testing results have been submitted for the PIL for the previously approved product, Acidex Compound Alginate Oral Suspension Heartburn and Indigestion Liquid originally approved as Acidex liquid to Pinewood Laboratories Limited on 25th March 1998 (PL 04917/0021). The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that they contain. As the already approved PIL is similar to the PIL for the proposed product, this is satisfactory.

MAA Form
The MAA forms are pharmaceutically satisfactory.

Quality Overall Summary
The quality overall summary has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical dossier.

Conclusion
It is recommended that Marketing Authorisations are granted for these applications from a quality point of view.
NON-CLINICAL ASSESSMENT

The pharmacodynamics, pharmacokinetics and toxicological properties of sodium alginate, sodium bicarbonate and calcium carbonate are well-known. As sodium alginate, sodium bicarbonate and calcium carbonate are widely used, well-known active substances, the applicant has not provided any additional studies and none are required. An overview based on literature review is therefore appropriate.

The non-clinical expert report has been written by an appropriately qualified person and is a suitable summary of the non-clinical aspects of the dossier.

A satisfactory justification was provided for the absence of an Environmental Risk Assessment.

It is recommended that Marketing Authorisations are granted for this application from a non-clinical point of view.
CLINICAL ASSESSMENT

Clinical Pharmacology
The applicant’s products are hybrid products of the reference product; oral suspensions with a mainly local (mechanical) effect within the gastro-intestinal tract, intended to act without systemic absorption. Therefore, as per the Guidance on the Investigation of Bioavailability and Bioequivalence CPMP/EWP/QWP/1401/98 Rev 1, a bioequivalence study based on systemic measurements is not required for these applications.

The product has twice as much sodium alginate as the reference product; therefore a smaller dosage volume dosage is required. The active ingredients and excipients remain well within safety margins.

Efficacy
No new efficacy data were submitted with these applications and none were required.

Safety
No new safety data were submitted with these applications and none were required.

Summary of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and Labelling
The SmPCs, PIL and labelling are clinically satisfactory and consistent with those for the reference product, where appropriate.

Clinical Overview
The clinical overview has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

MAA Forms
The MAA forms are clinically satisfactory.

Conclusions
It is recommended that Marketing Authorisations are granted for these applications from a clinical point of view.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data have been supplied with these applications and none are required for applications of this type.

EFFICACY
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension can be considered hybrid medicinal products to Gaviscon Liquid.

No new or unexpected safety concerns arise from these applications.

The SmPCs, PILs and labelling are satisfactory and consistent with those for the reference product.

RISK BENEFIT ASSESSMENT
The quality of the products is acceptable and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with sodium alginate, sodium bicarbonate and calcium carbonate is considered to have demonstrated the therapeutic value of the compounds. The risk benefit assessment is therefore considered to be positive.
ACIDEX MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

BOOTS MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the Marketing Authorisation application on 7th October 2009.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 27th October 2009.</td>
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<td>Following assessment of the applications, the MHRA requested further information on the clinical section of the dossier on 12th November 2009.</td>
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<td>Following assessment of the applications, the MHRA requested further information on the quality section of the dossier on 19th January 2012.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the clinical section of the dossier on 18th November 2009.</td>
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<td>The applicant responded to the MHRA’s requests, providing further information on the quality section of the dossier on 31st January 2012.</td>
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<td>5</td>
<td>The application was approved on 24th February 2012.</td>
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ACIDEX MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

BOOTS MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION (ANISEED/PEPPERMINT FLAVOUR)

**STEPS TAKEN AFTER AUTHORISATION - SUMMARY**

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<th>Application type</th>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Acidex Max Strength Heartburn Relief Oral Suspension (Aniseed Flavour)
Peptac Max Strength Heartburn Relief Oral Suspension (Aniseed Flavour)
Boots Max Strength Heartburn Relief Oral Suspension (Aniseed Flavour)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 10 ml contains:
- Sodium Alginate 1000 mg
- Sodium Bicarbonate 200 mg
- Calcium Carbonate 200 mg

Excipients include:
- Ethyl parahydroxybenzoate (E214) 15.0 mg/10 ml
- Propyl parahydroxybenzoate (E216) 5.50 mg/10 ml
- Butyl parahydroxybenzoate 2.50 mg/10 ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Oral Suspension,
Aniseed flavoured white or cream coloured suspension

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
Alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
For oral use

| Adults and children over 12 years and the Elderly: | 5 – 10 ml |
| Children under 12 years: | only under medical supervision |

Doses should be taken after meals and at bedtime.

4.3 CONTRAINDICATIONS
Hypersensitivity to any of the ingredients of this medicinal product, including the esters of hydroxybenzoates (Parabens) (see section 6.1).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
1) Treatment of children younger than 12 years of age is not generally recommended, except on medical advice

2) This medicinal product contains about 7.5 mmol of sodium per 10ml dose. To be taken into consideration by patients on a controlled sodium diet e.g. in cases of cardiac failure and renal impairment.

3) Each 10 ml contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

4) Compound Alginate Oral suspensions should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

5) Parahydroxybenzoates (E214, E216) may cause allergic reactions (possibly delayed)

6) If symptoms do not improve after seven days, medical advice should be sought.

7) There is a possibility of reduced efficacy in patients with very low levels of gastric acid.
4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

1) Antacids may interact with other drugs as they alter the gastric pH which may affect dissolution, solubility or ionization of the other drug. Antacids reduce the absorption of certain drugs from the following groups: ACE Inhibitors, Analgesics, Antibacterials, Antiepileptics, Antifungals, Antimalarials, Antipsychotics, Bisphosphonates, Lithium and Penicillamine.

2) Antacids may increase the pH of the urine and affect the rate of drug elimination. Excretion of basic drugs is decreased whereas acidic drugs are eliminated more rapidly.

3) Due to effects at the renal level sodium bicarbonate may reduce plasma lithium levels and increase plasma quinidine levels.

4.6 FERTILITY, PREGNANCY AND LACTATION

An open, uncontrolled study in 146 pregnant women did not demonstrate any significant adverse effects of this product on the course of pregnancy or on the health of the fetus/new-born child. No effects during pregnancy are anticipated, since systemic exposure to this product is negligible. This product can be used during pregnancy. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to this product is negligible. Based on this and previous experience this product may be used during pregnancy and lactation, however it is recommended to limit the treatment duration as much as possible.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

There are no known effects on ability to drive or operate machinery.

4.8 UNDESIRABLE EFFECTS

Constipation, flatulence, stomach cramps or belching may occasionally occur. Very rarely, in less than one in ten-thousand cases, patients sensitive to the ingredients develop allergic manifestations such as bronchospasm, urticaria, and anaphylaxis.

4.9 OVERDOSE

As Compound Alginate Oral suspensions mode of action is physical, overdosage in terms of the alginate content is virtually no hazard. The only consequence is abdominal distension which is best treated conservatively. The relatively low concentrations of sodium and calcium carbonate in this product would also make serious consequences from overdosage very unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC Code: A02BX13
Pharmaceutical group: Other drugs for peptic ulcer and gastro-oesophageal reflux

When taken after a meal Sodium Alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft.

5.2 PHARMACOKINETIC PROPERTIES

The mode of action of the product is physical and does not depend on absorption into the systemic circulation.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Carbomer
Sodium Hydroxide
Saccharin Sodium
Ethyl Parahydroxybenzoate (E214)
Propyl Parahydroxybenzoate (E216)
Butyl Parahydroxybenzoate
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)  PL 04917/0113-4
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

Isopropyl Alcohol
Aniseed Oil
Purified Water

6.2 INCOMPATIBILITIES
None known.

6.3 SHELF LIFE
24 months
Use within 3 months of opening

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C. Do not refrigerate or freeze.

6.5 NATURE AND CONTENTS OF CONTAINER
Pharmaceutical Grade Type III amber glass bottles with white polypropylene caps that have a Low density Polyethylene (LDPE) liner
Pack sizes: 150ml, 200ml, 250ml and 500ml.

Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
Shake bottle well before use

7 MARKETING AUTHORISATION HOLDER
Pinewood Laboratories Limited,
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)
PL 04917/0113

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
24/02/2012

10 DATE OF REVISION OF THE TEXT
24/02/2012
1 **NAME OF THE MEDICINAL PRODUCT**
Acidex Max Strength Heartburn Relief Oral Suspension (Peppermint Flavour)
Peptac Max Strength Heartburn Relief Oral Suspension (Peppermint Flavour)
Boots Max Strength Heartburn Relief Oral Suspension (Peppermint Flavour)

2 **QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each 10 ml contains:
- Sodium Alginate: 1000 mg
- Sodium Bicarbonate: 200 mg
- Calcium Carbonate: 200 mg

Excipients include:
- Ethyl parahydroxybenzoate (E214): 15.0 mg/10 ml
- Propyl parahydroxybenzoate (E216): 5.50 mg/10 ml
- Butyl parahydroxybenzoate: 2.50 mg/10 ml

For a full list of excipients, see section 6.1

3 **PHARMACEUTICAL FORM**
Oral Suspension,
Peppermint flavoured white or cream coloured suspension

4 **CLINICAL PARTICULARS**

4.1 **THERAPEUTIC INDICATIONS**
Alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

4.2 **POSOLOGY AND METHOD OF ADMINISTRATION**
For oral use

| Adults and children over 12 years and the Elderly: | 5 – 10 ml |
| Children under 12 years: | only under medical supervision |

Doses should be taken after meals and at bedtime.

4.3 **CONTRAINDICATIONS**
Hypersensitivity to any of the ingredients of this medicinal product, including the esters of hydroxybenzoates (Parabens) (see section 6.1).

4.4 **SPECIAL WARNINGS AND PRECAUTIONS FOR USE**
1) Treatment of children younger than 12 years of age is not generally recommended, except on medical advice
2) This medicinal product contains about 7.5 mmol of sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet e.g. in cases of cardiac failure and renal impairment.
3) Each 10 ml contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
4) Compound Alginate Oral suspensions should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.
5) Parahydroxybenzoates (E214, E216) may cause allergic reactions (possibly delayed)
6) If symptoms do not improve after seven days, medical advice should be sought.
7) There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

4.5 **INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**
1) Antacids may interact with other drugs as they alter the gastric pH which may affect dissolution, solubility or ionization of the other drug. Antacids reduce the absorption of certain
drugs from the following groups: ACE Inhibitors, Analgesics, Antibacterials, Antiepileptics, Antifungals, Antimalarials, Antipsychotics, Bisphosphonates, Lithium and Penicillamine.

2) Antacids may increase the pH of the urine and affect the rate of drug elimination. Excretion of basic drugs is decreased whereas acidic drugs are eliminated more rapidly.

3) Due to effects at the renal level sodium bicarbonate may reduce plasma lithium levels and increase plasma quinidine levels.

4.6 FERTILITY, PREGNANCY AND LACTATION
An open, uncontrolled study in 146 pregnant women did not demonstrate any significant adverse effects of this product on the course of pregnancy or on the health of the fetus/new-born child. No effects during pregnancy are anticipated, since systemic exposure to this product is negligible. This product can be used during pregnancy. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to this product is negligible. Based on this and previous experience this product may be used during pregnancy and lactation, however it is recommended to limit the treatment duration as much as possible.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
There are no known effects on ability to drive or operate machinery.

4.8 UNDESIRABLE EFFECTS
Constipation, flatulence, stomach cramps or belching may occasionally occur. Very rarely, in less than one in ten-thousand cases, patients sensitive to the ingredients develop allergic manifestations such as bronchospasm, urticaria, and anaphylaxis.

4.9 OVERDOSE
As Compound Alginate Oral suspensions mode of action is physical, overdosage in terms of the alginate content is virtually no hazard. The only consequence is abdominal distension which is best treated conservatively. The relatively low concentrations of sodium and calcium carbonate in this product would also make serious consequences from overdosage very unlikely.

5 PHARMACOLOGICAL PROPERTIES
5.1 PHARMACODYNAMIC PROPERTIES
ATC Code: A02BX13
Pharmaceutical group: Other drugs for peptic ulcer and gastro-oesophageal reflux

When taken after a meal Sodium Alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft.

5.2 PHARMACOKINETIC PROPERTIES
The mode of action of the product is physical and does not depend on absorption into the systemic circulation.

5.3 PRECLINICAL SAFETY DATA
There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS
6.1 LIST OF EXCIPIENTS
Carbomer
Sodium Hydroxide
Saccharin Sodium
Ethyl Parahydroxybenzoate (E214)
Propyl Parahydroxybenzoate (E216)
Butyl Parahydroxybenzoate
Isopropyl Alcohol
Peppermint Oil
Purified Water
6.2  INCOMPATIBILITIES
None known.

6.3  SHELF LIFE
24 months
Use within 3 months of opening

6.4  SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C. Do not refrigerate or freeze.

6.5  NATURE AND CONTENTS OF CONTAINER
Pharmaceutical Grade Type III amber glass bottles with white polypropylene caps that have a Low
density Polyethylene (LDPE) liner
Pack sizes: 150ml, 200ml, 250ml and 500ml.

Not all pack sizes may be marketed.

6.6  SPECIAL PRECAUTIONS FOR DISPOSAL
Shake bottle well before use

7  MARKETING AUTHOURISATION HOLDER
Pinewood Laboratories Limited,
Ballymacarby,
Clonmel,
Co. Tipperary,
Ireland.

8  MARKETING AUTHOURISATION NUMBER(S)
PL 04917/0114

9  DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHOURISATION
24/02/2012

10 DATE OF REVISION OF THE TEXT
24/02/2012
Please note that there is no mock-up available for Boots Max Strength Heartburn Relief Oral Suspension. The marketing authorisation holder has stated that it does not currently intend to market the product; therefore no UK-specific documents have been submitted. The marketing authorisation holder has committed to submit the UK PIL to the regulatory authority for review before marketing the product.

**IN THIS LEAFLET:**

1. **WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR**
   Max Strength Heartburn Relief belongs to a group of medicines called “reflux suppressants”. Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. **BEFORE YOU TAKE THIS MEDICINE**
   Do not take Max Strength Heartburn Relief if you:
   - are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2).
   Take special care with Max Strength Heartburn Relief
   You must tell your doctor or pharmacist and take special care if you are:
   - on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2).

**PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION**

**sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml, calcium carbonate 200 mg/10 ml**

**PACKAGE LEAFLET INFORMATION FOR THE USER**

Read all of this leaflet carefully before you start taking this medicine. This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:

- ACE inhibitors
- Analgesics
- Antibacterials
- Antiepileptics
- Antihistamines
- Antimalarials
- Antipsychotics
- Bisphosphonates
- Lithium
- Penicillamine

**Taking this medicine with food and drink**

This medicine should be taken after meals and at bedtime.

**Pregnancy and breast-feeding**

This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

**Driving and using machines**

There are no known effects of this medicine on ability to drive or operate machinery.

**Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)**

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 1000 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains parahydroxybenzoates (Parabens), E214 and E210 which may cause allergic reactions (possibly delayed). This medicinal product contains about 0.5 mmoles of sodium per 10 ml. Be taken into consideration by patients on a controlled sodium diet. Care should also be taken if on calcium controlled diet. Read the attached leaflet carefully before use. Do not take any more than the daily dose and have any bad problems. Shake well before use. Leave 3 hours between taking this medicine and other medicines. KEEP OUT OF THE REACH AND SIGHT OF CHILDREN. Take special care if you are allergic to any of the ingredients of this medicine. Side effects are occasional. See leaflet for further information. Store below 25°C. Do not use after the expiry date shown on the label. Did not regrapte or freeze. Marketing Authorisation Holder: Pinewood Laboratories Limited, Ballymacarthy, Clemmie, Co. Tipperary, Ireland PL 04917/0113- 14710-A 2011.
## Important information about some of the ingredients of Max Strength Heartburn Relief

**This medicine also contains:**
- **Parahydroxyzine:** may cause allergic reactions, possibly delayed
- **Sodium:** Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

### HOW TO TAKE THIS MEDICINE

To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly | 5 – 10 ml |
| Children under 12 years | only under medical supervision |

### VERY RARELY

- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face. If this occurs you should stop taking the medicine and seek immediate medical attention.

### OCCASIONAL

- Constipation
- Flatulence
- Stomach cramp
- Belching.

### POSSIBLE SIDE EFFECTS

Like all medicines, this product can cause side effects, although not everybody gets them.

### WARNING: DO NOT EXCEED THE STATED DOSE

If you take more of this medicine than you should

Overdose is very unlikely but if it occurs it may cause bloating.

If you forget to take Max Strength Heartburn Relief

If you forget to take your medicine, take it as soon as you remember. Do not take a double dose to make up for the forgotten dose.

### FURTHER INFORMATION

**What Max Strength Heartburn Relief contains:**
- The active ingredients are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The other ingredients are: Carbonate, Sodium Hydroxide, Succharin Sodium, Ethyl Parahydroxyzine (E214), Propyl Parahydroxyzine (E216), Butyl Parahydroxyzine, Isopropyl Alcohol, Anised Oil and Purified Water (see end of Section 2 for further information).

**What Max Strength Heartburn Relief looks like and contents of the pack**

This medicine is an anised flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polythene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 220 ml, 250 ml and 500 ml with white polypropylene caps.

Not all pack sizes may be marketed.

**Manufacturer / Marketing Authorisation Holder**
Pinewood Laboratories Limited,
Ballymacarbry,
Cronmel,
Co. Tipperary,
Ireland.

PL 04917/0113

**Distributed by:** TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last updated in 12/2011
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)

Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

Max Strength Heartburn Relief belongs to a group of medicines called “reflux suppressants”. Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

BEFORE YOU TAKE THIS MEDICINE

Do not take Max Strength Heartburn Relief if you:
• are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2);

Take special care with Max Strength Heartburn Relief

You must tell your doctor or pharmacist and take special care if you are:
• on a sodium restricted diet or suffer from too much calcium in the blood (see end of Section 2);
• Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

TAKING OTHER MEDICINES

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:
• ACE inhibitors
• Analgesics
• Antibacterials
• Antidiabetics
• Antifungals
• Antidepressants
• Antipsychotics
• Bisphosphonates
• Lithium
• Pericillin.

TAKING THIS MEDICINE WITH FOOD AND DRINK

This medicine should be taken after meals and at bedtime.

Pregnancy and breastfeeding

This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.
Driving and using machines
There are no known effects of this medicine on ability to drive or operate machinery.

Important information about some of the ingredients of Max Strength Heartburn Relief
This medicine also contains:
- Parahydroxybenzoates: may cause allergic reactions, possibly delayed
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3 HOW TO TAKE THIS MEDICINE
To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly: | 5 - 10 ml |
| Children under 12 years: | only under medical supervision |

WARNING: DO NOT EXCEED THE STATED DOSE

4 POSSIBLE SIDE EFFECTS
Like all medicines, this product can cause side effects, although not everybody gets them.
Very rarely:
- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face. If this occurs you should stop taking the medicine and seek immediate medical attention.

Occasional:
- Constipation
- Flatulence
- Stomach cramp
- Belching.
If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE THIS MEDICINE
Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze.
Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION
What Max Strength Heartburn Relief contains:
- The active ingredients are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The other ingredients are: Carbomer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Aniseed Oil and Purified Water (see end of Section 2 for further information).

What Max Strength Heartburn Relief looks like and contents of the pack
This medicine is an aniseed flavoured white or cream coloured suspension.

It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps.
Not all pack sizes may be marketed.

Manufacturer / Marketing Authorisation Holder
Pinewood Laboratories Limited,
Ballymacarbery,
Clonmel,
Co. Tipperary,
Ireland.
PL 04917/0113

Distributed by: TEVA UK Limited, Eastbourne, BN22 9AG.
This leaflet was last updated in 12/2011

TEVA
TEVA LIMITED
PACKAGE LEAFLET: INFORMATION FOR THE USER

Acidex Max Strength Heartburn Relief Oral Suspension
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml and calcium carbonate 200 mg/10 ml

Read all of this leaflet carefully before you start taking this medicine.

This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What this medicine is and what it is used for.
2. Before you take this medicine.
3. How to take this medicine.
4. Possible side effects.
5. How to store this medicine.
6. Further information.

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

Max Strength Heartburn Relief belongs to a group of medicines called "reflux suppressants". Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE

Do not take Max Strength Heartburn Relief if you:
- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 4 and end of Section 2).

Take special care with Max Strength Heartburn Relief

You must tell your doctor or pharmacist and take special care if you are:
- on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2).
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

TAKING OTHER MEDICINES

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:
- ACE inhibitors
- Analgesics
- Antibacterials
- Anticonvulsants
- Antihistamines
- Antifungals
- Antifungals

Taking this medicine with food and drink

This medicine should be taken after meals and at bedtime.

PREGNANCY AND BREAST-FEEDING

This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

DRIVING AND USING MACHINES

There are no known effects of this medicine on ability to drive or operate machinery.

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains: sodium lauryl sulfate, polyester resin, FD&C Blue No 2, FD&C Red No 40, FD&C Yellow No 6 and water. Sputum colour may be dark red or brown. The medicated product contains about 2.5 mEq of sodium per 10 ml dose. To be taken into consideration if on a controlled sodium diet. Care should also be taken if on an calcium controlled diet. Read the attached leaflet carefully before use. It is to be taken 1 hour after meals and at bedtime. Store one well before use. Leave 1 hour between taking this medicine and other medicines. Keep out of the reach and sight of children. Take special care if you are aged 65 or over. See the ingredients list for further information. Store below 25°C. Do not use after the expiry date shown on the label. Do not refrigerate or freeze.

Marketing Authorisation Holder: GSK Consumer Healthcare Limited, Box 609, Salford M6 9PY, UK. Batch: PL 04917/0113-4 GSK
Important information about some of the ingredients of Max Strength Heartburn Relief

This medicine also contains:
- Parahydroxybenzoates: may cause allergic reactions, possibly delayed.
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3. **HOW TO TAKE THIS MEDICINE**

To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly: | 5 – 10 ml |
| Children under 12 years: | only under medical supervision |

**WARNING: DO NOT EXCEED THE STATED DOSE**

If you take more of this medicine than you should
Overdose is very unlikely but if it occurs it may cause bloating.

If you forget to take Max Strength Heartburn Relief
If you forget to take your medicine, take it as soon as you remember, Do not take a double dose to make up for the forgotten dose.

4. **POSSIBLE SIDE EFFECTS**

Like all medicines, this product can cause side effects, although not everybody gets them.

**Very rarely:**
- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face.

If this occurs you should stop taking the medicine and seek immediate medical attention.

**Occasional:**
- Constipation
- Flatulence
- Stomach cramp
- Belching

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE THIS MEDICINE**

Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. **FURTHER INFORMATION**

What Max Strength Heartburn Relief contains:
- The **active ingredients** are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The **other ingredients** are: Carbomer, Sodium Hydroxide, Succharrum Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Anised Oil, and Purified Water (see end of Section 2 for further information)

What Max Strength Heartburn Relief looks like and contents of the pack
This medicine is an aniseed flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polyethylene, aluminium and partial zine salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps. Not all pack sizes may be marketed.

Manufacturer/Marketing Authorisation Holder
Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0113

This leaflet was last updated in 12/2011
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)         PL 04917/0113-4
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

In this leaflet:
1. What this medicine is and what it is used for
2. Before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Further information

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR
Max Strength Heartburn Relief belongs to a group of medicines called “reflux suppressants”. Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE
Do not take Max Strength Heartburn Relief if you:
• are allergic (hypersenstive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2)
• Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Max Strength Heartburn Relief should not be taken within 1 to 2 hours
of taking other medicines by mouth, or for more than 7 days if symptoms persist.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently
taken, any other medicines, including medicines obtained without a
prescription and especially if you are taking any of the following, as
interactions can occur:
• ACE inhibitors
• Analgesics
• Antibacterials
• Antiepileptics
• Antitussives
• Antimalarials

• Antipsychotics
• Bisphosphonates
• Lithium
• Penicillamine

Taking this medicine with food and drink
This medicine should be taken after meals and at bedtime.

Pregnancy and breast-feeding
This medicine can be used during pregnancy and breast-feeding, however
it is recommended to limit the treatment duration as much as possible.

Driving and using machines
There are no known effects of this medicine on ability to drive or
operate machinery.

Each 10 ml of the oral suspension contains 1000 mg
of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains
hydroxybenzoates (Parabens, E214 and E216) which may cause allergic reactions (possibly delayed).
This medicinal product contains about 7.5 mg/ml of sodium for 10 ml to be taken into consideration.
Take with a glass of water. Do not exceed the daily dose stated on the label. Do not refrigerate or freeze.

25
Important information about some of the ingredients of Max Strength Heartburn Relief

This medicine also contains:
- Parahydroxybenzoate: may cause allergic reactions, possibly delayed
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3. HOW TO TAKE THIS MEDICINE

To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

- Adults and children over 12 years and the Elderly:
  - 5 - 10 ml

- Children under 12 years:
  - only under medical supervision

WARNING: DO NOT EXCEED THE STATED DOSE

If you take more of this medicine than you should

Overdose is very unlikely but if it occurs it may cause bloating.

If you forgot to take Max Strength Heartburn Relief

If you forget to take your medicine, take it as soon as you remember.

Do not take a double dose to make up for the forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this product can cause side effects, although not everybody gets them.

Very rarely:
- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face.

If this occurs you should stop taking the medicine and seek immediate medical attention.

Occasional:
- Constipation
- Flatulence
- Stomach cramp
- Bloating

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE THIS MEDICINE

Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Max Strength Heartburn Relief contains:

- The active ingredients are: Calcium Carbonate 200 mg/10 ml and Sodium bicarbonate 200 mg/10 ml
- The other ingredients are: Carboxer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropl Alcohol, Aniseed Oil and Purified Water (see end of Section 2 for further information)

What Max Strength Heartburn Relief looks like and contents of the pack

This medicine is an aniseed flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps. Not all pack sizes may be marketed.
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)  
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)  

PACKAGE LEAFLET: INFORMATION FOR THE USER  
Acidex Max Strength Heartburn Relief Oral Suspension  
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml  
and calcium carbonate 200 mg/10 ml  

Read all of this leaflet carefully before you start taking this medicine.  
This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.  
- Keep this leaflet. You may need to read it again.  
- If you have any further questions, ask your doctor or pharmacist.  
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:  
1. What this medicine is and what it is used for  
2. Before you take this medicine  
3. How to take this medicine  
4. Possible side effects  
5. How to store this medicine  
6. Further information

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR  
Max Strength Heartburn Relief belongs to a group of medicines called "reflux suppressants". Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE  
Do not take Max Strength Heartburn Relief if you:  
- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2)  
- Take special care with Max Strength Heartburn Relief  
You must tell your doctor or pharmacist and take special care if you are:  
- on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2)  
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

Taking other medicines  
Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:
- ACE inhibitors
- Antidepressants
- Antibacterials
- Antiepileptics
- Antifungals
- Antimalarials

Taking this medicine with food and drink.
This medicine should be taken after meals and at bedtime.

Pregnancy and breast-feeding  
This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

Driving and using machines  
There are no known effects of this medicine on ability to drive or operate machinery.

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains carboxymethylcellulose (Parabens, E211 and E210) which may cause local reactions (possibly delayed). This medicine (product) contains about 5.5 mmol (0.1 g) of sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet. This should also be taken on a calcium controlled diet. Hold the attached lozenges carefully before use. To be taken by mouth after meals and at bedtime. Should not be taken within 1 to 2 hours of taking other medicines or other medicines. Keep out of the reach and sight of children. Take special care if you are using to treat the symptoms of ulcers. For side effects, see Annex. See leaflet for further information. Store below 25°C. Do not use after the expiry date shown on the label. Do not refrigerate or freeze.
Marketing Authorisation Holder: Jephson Laboratories Limited, Shamrock Park, Limerick, Ireland. Licence: PL 04917/0113. 28 LIL.
Important information about some of the ingredients of Max Strength Heartburn Relief

This medicine also contains:
- **Parahydroxybenzoates**: may cause allergic reactions, possibly delayed.
- **Sodium**: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3. **HOW TO TAKE THIS MEDICINE**

   To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly | 5 – 10 ml |
| Children under 12 years | only under medical supervision |

**WARNING: DO NOT EXCEED THE STATED DOSE**

If you take more of this medicine than you should
Overdose is very unlikely but if it occurs it may cause bloating.

If you forgot to take Max Strength Heartburn Relief
If you forgot to take your medicine, take it as soon as you remember,
Do not take a double dose to make up for the forgotten dose.

4. **POSSIBLE SIDE EFFECTS**

   Like all medicines, this product can cause side effects, although not everybody gets them.

   Very rarely:
   - Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face.

   If this occurs you should stop taking the medicine and seek immediate medical attention.

   Occasional:
   - Constipation
   - Flatulence
   - Stomach cramp
   - Belching

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE THIS MEDICINE**

   Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use the product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. **FURTHER INFORMATION**

   What Max Strength Heartburn Relief contains:
   - The active ingredients are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
   - The other ingredients are: Carobomer, Sodium Hydroxide, Sascharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Aniseed Oil, and Purified Water (see end of Section 2 for further information)

   What Max Strength Heartburn Relief looks like and contents of the pack
   This medicine is an aniseed flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps. Not all pack sizes may be marketed.

Manufacturer/Marketing Authorisation Holder
Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0113

This leaflet was last updated in 12/2011
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

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**PACKAGE LEAFLET: INFORMATION FOR THE USER**
Acidex Max Strength Heartburn Relief Oral Suspension
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml
and calcium carbonate 200 mg/10 ml

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Read all of this leaflet carefully before you start taking this medicine.
This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What this medicine is and what it is used for
2. Before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Further information

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1. **WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR**
Max Strength Heartburn Relief belongs to a group of medicines called "reflux suppressants". Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. **BEFORE YOU TAKE THIS MEDICINE**
Do not take Max Strength Heartburn Relief if you:
- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2)

Take special care with Max Strength Heartburn Relief
You must tell your doctor or pharmacist and take special care if you are:

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- on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2)
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:
- ACE inhibitors
- Analgesics
- Antibacterials
- Antiepileptics
- Antifungals
- Antimalarials
- Antipsychotics
- Bisphosphonates
- Lithium
- Pencillamine

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**GSL**
Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains hydroxybenzoates (Parabens, E214 and E216) which may cause allergic reactions (possibly delayed).
This medicinal product contains about 7.5 mmol of sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet. Care should also be taken if on calcium controlled diet. Read the attached leaflet carefully before use. To be taken by mouth after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. Keep out of the reach and sight of children. Take special care if you are allergic to any of the ingredients of this medicine.
Side effects are occasional. See leaflet for further information.
Store below 25°C. Do not use after the expiry date shown on the label. Do not refrigerate or freeze.

**Marketing Authorisation Holder:**
Pinewood Laboratories Limited, Ballymacarbery, Clonmel, Co. Tipperary, Ireland
PL 04917/0113 2011

GSL
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

**Taking this medicine with food and drink**
This medicine should be taken after meals and at bedtime.

**Pregnancy and breast-feeding**
This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

**Driving and using machines**
There are no known effects of this medicine on ability to drive or operate machinery.

**Important information about some of the ingredients of Max Strength Heartburn Relief**
This medicine also contains:
- **Parahydroxycarboxylic acid** may cause allergic reactions, possibly delayed.
- **Sodium**: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

**3. HOW TO TAKE THIS MEDICINE**
To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly: | 5 – 10 ml |
| Children under 12 years: | only under medical supervision |

**WARNING: DO NOT EXCEED THE STATED DOSE**
If you take more of this medicine than you should
Overdose is very unlikely but if it occurs it may cause bloating.

If you forget to take Max Strength Heartburn Relief
If you forget to take your medicine, take it as soon as you remember, Do not take a double dose to make up for the forgotten dose.

**4. POSSIBLE SIDE EFFECTS**
Like all medicines, this product can cause side effects, although not everybody gets them.

**Very rarely:**
- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face.

If this occurs you should stop taking the medicine and seek immediate medical attention.

**Occasional:**
- Constipation
- Flatulence
- Stomach cramp
- Belching

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE THIS MEDICINE**
Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**
What Max Strength Heartburn Relief contains:
- **The active ingredients are:** Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- **The other ingredients are:** Carbomer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Aniseed Oil, and Purified Water (see end of Section 2 for further information)

What Max Strength Heartburn Relief looks like and contents of the pack
This medicine is an aniseed flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps. Not all pack sizes may be marketed.

**Manufacturer/Marketing Authorisation Holder**
Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
PL 04917/0113

This leaflet was last updated in 12/2011
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)  
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)  
PL 04917/0113-4

PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml, calcium carbonate 200 mg/10 ml

PACKAGE LEAFLET INFORMATION FOR THE USER
Read all of this leaflet carefully before you start taking this medicine.
This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR
Max Strength Heartburn Relief belongs to a group of medicines called "reflux suppressants". Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients:
- sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE
Do not take Max Strength Heartburn Relief if you:
- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzenes (parabens) (see Section 6 and end of Section 2).
- Take special care with Max Strength Heartburn Relief
You must tell your doctor or pharmacist and take special care if you are:
- on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2).

Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.
Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:
- ACE inhibitors
- Analgesics
- Antibacterials
- Antiepileptics
- Antihistamines
- Antimalarials
- Antipsychotics
- Bisphosphonates
- Lithium
- Penicillamine.

Taking this medicine with food and drink
This medicine should be taken after meals and at bedtime.

Pregnancy and breast-feeding
This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

Driving and using machines
There are no known effects of this medicine on ability to drive or operate machinery.

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 400 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains parahydroxybenzoate (Parabens), E214 and E218 which may cause allergic reactions (possibly delayed). This medicine contains 7.5 mmol of sodium per 10 ml, to be taken into consideration by patients on a controlled sodium diet. Care should also be taken on calcium controlled diet. Read the attached leaflet carefully before use. Do not take by mouth after meals and at bedtime. Shake well before use. Leave 1-2 hours between taking this medicine and other medicines. KEEP OUT OF THE REACH AND SIGHT OF CHILDREN. Take special care if you are allergic to any of the ingredients of this medicine. Side effects may occur. See leaflet for further information. Store below 25°C. Do not refrigerate or freeze. Marketing Authorisations Holder: Pinewood Laboratories Limited, Bailymacarry, Clonmel, Co. Tipperary, Ireland. PL 04917/0114 14713 A 28L © UK MED 41M

31
Important information about some of the ingredients of Max Strength Heartburn Relief

This medicine also contains:

- Parahydroxybenzoates: may cause allergic reactions, possibly delayed
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

HOW TO TAKE THIS MEDICINE

To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly | 5 – 10 ml |
| Children under 12 years | only under medical supervision |

WARNING: DO NOT EXCEED THE STATED DOSE

If you take more of this medicine than you should
Overdose is very unlikely but if it occurs it may cause bloating.

If you forget to take Max Strength Heartburn Relief
If you forget to take your medicine, take it as soon as you remember. Do not take a double dose to make up for the forgotten dose.

POSSIBLE SIDE EFFECTS

Like all medicines, this product can cause side effects, although not everybody gets them.

VERY RARELY:

- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face. If this occurs you should stop taking the medicine and seek immediate medical attention.

OCCASIONAL:

- Constipation
- Flatulence
- Stomach cramp
- Belching.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

HOW TO STORE THIS MEDICINE

Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze.

Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

FURTHER INFORMATION

What Max Strength Heartburn Relief contains:

- The active ingredients are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The other ingredients are: Carbomer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Peppermint Oil and Purified Water (see end of Section 2 for further information).

What Max Strength Heartburn Relief looks like and contents of the pack

This medicine is a peppermint flavoured white or cream coloured suspension.

It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps.

Not all pack sizes may be marketed.

Manufacturer / Marketing Authorisation Holder

Pinewood Laboratories Limited, Ballymacarbery, Clonmel, Co. Tipperary, Ireland.

PL 04917/0114

Distributed by: TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last updated in 12/2011
UKPAR Acide/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)         PL 04917/0113-4
Acide/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

PEPTAC MAX STRENGTH HEARTBURN RELIEF ORAL SUSPENSION
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml, calcium carbonate 200 mg/10 ml

PACKAGE LEAFLET INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.
This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:
1. What this medicine is and what it is used for
2. Before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Further information

WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR
Max Strength Heartburn Relief belongs to a group of medicines called “reflux suppressants”. Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

BEFORE YOU TAKE THIS MEDICINE
Do not take Max Strength Heartburn Relief if you:

- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2).

Take special care with Max Strength Heartburn Relief
You must tell your doctor or pharmacist and take special care if you are:

- on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2)
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains parahydroxybenzoates (Parabens, E214 and E216) which may cause allergic reactions (possibly delayed). This medicinal product contains about 7.5 mmol of sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet. Care should also be taken if on a calcium controlled diet. Read the attached leaflet carefully before use. To be taken by mouth after meals and at bedtime.

Shake well before use. Leave 1 to 2 hours between taking this medicine and other medicines. KEEP OUT OF THE REACH AND SIGHT OF CHILDREN. Take special care if you are allergic to any of the ingredients of this medicine. Side effects are also listed. See listing for further information. Store below 25°C. Do not use after the expiry date shown on the label. Do not refrigerate or freeze.

Marketing Authorisation Holder:
Pinewood Laboratories Limited, Ballymacarbery, Clonmel, Co. Tipperary, Ireland.

Distributed by: TEVA UK Limited, Eastbourne, BN22 9AG. 14715-A 23LL

Peptac Max Strength Heartburn Relief Oral Suspension
sodium alginate, sodium bicarbonate, calcium carbonate

Peppermint flavour

Orel Suspension

Teva
Driving and using machines

There are no known effects of this medicine on ability to drive or operate machinery.

Important information about some of the ingredients of Max Strength Heartburn Relief

This medicine also contains:
- Parahydroxybenzoates: may cause allergic reactions, possibly delayed
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

HOW TO TAKE THIS MEDICINE

To be taken mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly: | 5 – 10 ml |
| Children under 12 years: | only under medical supervision |

WARNING: DO NOT EXCEED THE STATED DOSE

If you take more of this medicine than you should

Overdose is very unlikely but if it occurs it may cause bloating.

If you forget to take Max Strength Heartburn Relief

If you forget to take your medicine, take it as soon as you remember. Do not take a double dose to make up for the forgotten dose.

4 POSSIBLE SIDE EFFECTS

Like all medicines, this product can cause side effects, although not everybody gets them.

Very rarely:
- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face. If this occurs you should stop taking the medicine and seek immediate medical attention.

Occasional:
- Constipation
- Flatulence
- Stomach cramp
- Belching.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE THIS MEDICINE

Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze.

Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Max Strength Heartburn Relief contains:
- The active ingredients are: Sodium alginic 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The other ingredients are: Carbomer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Peppermint Oil and Purified Water (see end of Section 2 for further information).

What Max Strength Heartburn Relief looks like and contents of the pack

This medicine is a peppermint flavoured white or cream coloured suspension.

It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps.

Not all pack sizes may be marketed.

Manufacturer / Marketing Authorisation Holder

PL 04917/0114

Distributed by: TEVA UK Limited, Eastbourne, BN22 8AG

This leaflet was last updated in 12/2011
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

PACKAGE LEAFLET: INFORMATION FOR THE USER
Acidex Max Strength Heartburn Relief Oral Suspension
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml and calcium carbonate 200 mg/10 ml

Read all of this leaflet carefully before you start taking this medicine.
This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days:
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What this medicine is and what it is used for
2. Before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Further information

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR
Max Strength Heartburn Relief belongs to a group of medicines called "reflux suppressants". Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE
Do not take Max Strength Heartburn Relief if you:
- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2)

Take special care with Max Strength Heartburn Relief
You must tell your doctor or pharmacist and take special care if you are:
- on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2)
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:
- ACE inhibitors
- Antidepressants
- Anticoagulants
- Antibacterials
- Anticonvulsants
- Antimalarials

- Antipsychotics
- Bisphosphonates
- Lithium
- Perindopril

Taking this medicine with food and drink
This medicine should be taken after meals and at bedtime.

Pregnancy and breast-feeding
This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

Driving and using machines
There are no known effects of this medicine on ability to drive or operate machinery.

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains parahydroxybenzoates (parabens, E214 and E216) which may cause allergic reactions (possibly delayed). The medicinal product contains about 75 mmol of sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet. Care should also be taken if on calcium controlled diet. Read the attached leaflet carefully before use. To be taken by mouth. Store below 25°C. Do not take after the expiry date shown on the label. Do not refrigerate or freeze.

Marketing Authorisation Holder: Pigwood Laboratories Limited, Hadham Abbey, Dunmow, Essex, CM6 3TT, England PL 04917/0113-4
GSL

35
Important information about some of the ingredients of Max Strength Heartburn Relief
This medicine also contains:
- Parahydroxybenzoates: may cause allergic reactions, possibly delayed
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3. HOW TO TAKE THIS MEDICINE
To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this product can cause side effects, although not everybody gets them.

Very rarely:
- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face.
If this occurs you should stop taking the medicine and seek immediate medical attention.

Occasional:
- Constipation
- Flatulence
- Stomach cramp
- Belching

5. HOW TO STORE THIS MEDICINE
Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What Max Strength Heartburn Relief contains:
- The active ingredients are: Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The other ingredients are: Carbomer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Peppermint Oil, and Purified Water (see end of Section 2 for further information).
What Max Strength Heartburn Relief looks like and contents of the pack
This medicine is a peppermint flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps. Not all pack sizes may be marketed.

Manufacturer/Marketing Authorisation Holder
Pinewood Laboratories Limited, Ballymacarberry, Clonmel, Co. Tipperary, Ireland. PL 04917/0114
This leaflet was last updated in 12/2011
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)  
Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)  
PL 04917/0113-4

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:
- AN INHIBITORS
- Analgesics
- Antidepressants
- Antiepileptics
- Antimalarials
- Antipsychotics
- Bisphosphonates
- Lithium
- Penicillamine

Taking this medicine with food and drink
This medicine should be taken after meals and at bedtime.

Pregnancy and breast-feeding
This medicine can be used during pregnancy and breast-feeding, however, it is recommended to limit the treatment duration as much as possible.

Driving and using machines
There are no known effects of this medicine on ability to drive or operate machinery.

Package leaflet: Information for the User
Acidex Max Strength Heartburn Relief Oral Suspension
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml  
and calcium carbonate 200 mg/10 ml

Read all of this leaflet carefully before you start taking this medicine.
This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR
Max Strength Heartburn Relief belongs to a group of medicines called "reflux suppressants". Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE
Do not take Max Strength Heartburn Relief if you:
- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxycarboxylic acid (parabens) (see Sections 6 and end of Section 2)

Take special care with Max Strength Heartburn Relief
You must tell your doctor or pharmacist and take special care if you are:
- on a sodium restricted diet or suffer from too much calcium in the blood (see end of Section 2)
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Each 20 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains parahydroxybenzenes (Parabens, E214 and E216) which may cause allergic reactions (potentially delayed). This medicinal product contains about 7.5 mmol of sodium per 10 ml dose. To be taken into consideration by people on a controlled sodium diet. Care should also be taken if on calcium controlled diet. Read the label and use carefully before use. Do not exceed the recommended dose. Leave at least 2 hours between taking this medicine and other medicines. Keep out of the reach and sight of children. Take special care if you are allergic to any of the ingredients in this medicine. See harmful effects of this medicine. Seek medical advice if you are pregnant or breast-feeding. See additional information date before 25°C. Do not use after the expiry date shown on the label. Do not refrigerate or freeze.

Irish Stockist: PL 04917/0114 - ZSL.
Important information about some of the ingredients of Max Strength Heartburn Relief
This medicine also contains:
- Parahydroxybenzoates: may cause allergic reactions, possibly delayed
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3. HOW TO TAKE THIS MEDICINE
To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1–2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly: | 5 – 10 ml |
| Children under 12 years: | only under medical supervision |

WARNING: DO NOT EXCEED THE STATED DOSE
If you take more of this medicine than you should
Overdose is very unlikely but if it occurs it may cause bloating.

If you forget to take Max Strength Heartburn Relief
If you forgot to take your medicine, take it as soon as you remember, Do not take a double dose to make up for the forgotten dose.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this product can cause side effects, although not everybody gets them.

Very rarely:
- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face.

If this occurs you should stop taking the medicine and seek immediate medical attention.

Occasional:
- Constipation
- Flatulence
- Stomach cramp
- Belching

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE THIS MEDICINE
Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What Max Strength Heartburn Relief contains:
- The active ingredients are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The other ingredients are: Carbomer, Sodium Hydroxide, Saccharn Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Peppermint Oil, and Purified Water (see end of Section 2 for further information)

What Max Strength Heartburn Relief looks like and contents of the pack
This medicine is a peppermint flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps. Not all pack sizes may be marketed.

Manufacturer/Marketing Authorisation Holder
Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 0491760114

This leaflet was last updated in 12/2011
UKPAR Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (aniseed flavour)         PL 04917/0113-4

Acidex/Peptac/Boots Max Strength Heartburn Relief Oral Suspension (peppermint flavour)

PACKAGE LEAFLET: INFORMATION FOR THE USER
Acidex Max Strength Heartburn Relief Oral Suspension sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml and calcium carbonate 200 mg/10 ml

Read all of this leaflet carefully before you start taking this medicine.

This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What this medicine is and what it is used for
2. Before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Further information

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

Max Strength Heartburn Relief belongs to a group of medicines called "reflux suppressants". Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE

Do not take Max Strength Heartburn Relief if you:

- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (see Section 6 and end of Section 2)

Take special care with Max Strength Heartburn Relief

You must tell your doctor or pharmacist and take special care if you are:

- on a sodium restricted diet or suffer from too much sodium in the blood (see end of section 2)
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:

- Antipsychotics
- Bisphosphonates
- Lithium
- Penicillamine

Taking this medicine with food and drink

This medicine should be taken after meals and at bedtime.

Pregnancy and breast-feeding

This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

Driving and using machines

There are no known effects of this medicine on ability to drive or operate machinery.

Max Strength Heartburn Relief 250 ml Oral Suspension (aniseed flavour)

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 204 mg of calcium carbonate. Also contains parahydroxybenzoates (Parabens, E214 and E216), which may cause allergic reactions (possibly delayed). This medicinal product contains about 7.5 mmol (190 mg) of sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet. Care should also be taken if it is taken with a controlled diet. Read the product leaflet carefully before use. Do not be taken if you have a known allergy to any of the ingredients of this medicine. Store below 25°C. Do not use after the expiry date shown on the label. Do not refrigerate or freeze.


GSL
Important information about some of the ingredients of Max Strength Heartburn Relief

This medicine also contains:
- Parahydroxybenzoates: may cause allergic reactions, possibly delayed
- Sodium: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3. HOW TO TAKE THIS MEDICINE
To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

| Adults and children over 12 years and the Elderly: | 5 – 10 ml |
| Children under 12 years: | only under medical supervision |

4. POSSIBLE SIDE EFFECTS
Like all medicines, this product can cause side effects, although not everybody gets them.
- Very rarely:
  - Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face.
- If this occurs you should stop taking the medicine and seek immediate medical attention.
- Occasional:
  - Constipation
  - Flatulence
  - Stomach cramp
  - Belching

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE THIS MEDICINE
Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What Max Strength Heartburn Relief contains:
- The active ingredients are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The other ingredients are: Carboner, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Peppermint Oil, and Purified Water (see end of Section 2 for further information)

What Max Strength Heartburn Relief looks like and contents of the pack
This medicine is a peppermint flavoured white or cream coloured suspension. It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml and 500 ml with white polypropylene caps. Not all pack sizes may be marketed.

Manufacturer/Marketing Authorisation Holder
Pinewood Laboratories Limited, Ballymacarthy, Clonmel, Co. Tipperary, Ireland.
PL 04917/0114
This leaflet was last updated in 12/2011
PACKAGE LEAFLET: INFORMATION FOR THE USER

Acidex Max Strength Heartburn Relief Oral Suspension
sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml
and calcium carbonate 200 mg/10 ml

Read all of this leaflet carefully before you start taking this medicine.
This medicine is available without prescription. However, you still need to use the product
carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do
not improve after seven days.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects
  not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What this medicine is and what it is used for
2. Before you take this medicine
3. How to take this medicine

4. Possible side effects
5. How to store this medicine
6. Further information

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR
Max Strength Heartburn Relief belongs to a group of medicines called “reflux suppressants”.
Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause
pain and discomfort known as heartburn or acid indigestion. This medicine contains the active
ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a
protective layer at the top of your stomach to stop reflux from happening. It can therefore
be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

2. BEFORE YOU TAKE THIS MEDICINE
Do not take Max Strength Heartburn Relief if you:
- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of
  hydroxybenzoates (parabens) (see Section 6 and end of Section 2)

Take special care with Max Strength Heartburn Relief
You must tell your doctor or pharmacist and take special care if you are:

- on a sodium restricted diet or suffer from too much calcium in the blood (see end of section 2)
- Treatment of children younger than 12 years of age is not generally recommended, except on
  medical advice

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines
by mouth, or for more than 7 days if symptoms persist.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines,
including medicines obtained without a prescription and especially if you are taking any of the
following, as interactions can occur:
- ACE inhibitors
- Analgesics
- Antibacterials
- Antiepileptics
- Antifungals
- Antimalarials
- Antipsychotics
- Bisphosphonates
- Lithium
- Penicillamine

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate. Also contains parahydroxybenzoates (Parabens, E214
and E216) which may cause allergic reactions (possibly delayed). This medicinal product contains about 7.5 mmol of sodium per 10 ml dose. To be taken into consideration by patients on a controlled
sodium diet. Care should also be taken if on calcium controlled diet.
Read the attached label carefully before use. To be taken by mouth after meals and at bedtime. Shake bottle well before use.
Leave 1-2 hours between taking this medicine and other medicines.
Keep out of the reach and sight of children. Take special care if you are allergic to any of the ingredients of this medicine.
Side effects are occasional. See leaflet for further information.
Store below 25°C. Do not use after the expiry date shown on the
label. Do not refrigerate or freeze.

Marketing Authorisation Holder:
Pinewood Laboratories Limited, Ballymacarbery, Glinmel, Co. Tipperary, Ireland
PL 04917/0114 23LL
Taking this medicine with food and drink
This medicine should be taken after meals and at bedtime.

Pregnancy and breast-feeding
This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

Driving and using machines
There are no known effects of this medicine on ability to drive or operate machinery.

Important information about some of the ingredients of Max Strength Heartburn Relief
This medicine also contains:
- **Parahydroxybenzoates**: may cause allergic reactions, possibly delayed
- **Sodium**: Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

3. **HOW TO TAKE THIS MEDICINE**
To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

If this occurs you should stop taking the medicine and seek immediate medical attention.

Occasional:
- Constipation
- Flatulence
- Stomach cramp
- Belching

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE THIS MEDICINE**
Keep out of the reach and sight of children. Do not store above 25°C. Do not refrigerate or freeze. Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

42
Please note that there is no mock-up available for Boots Max Strength Heartburn Relief Oral Suspension. The marketing authorisation holder has stated that it does not currently intend to market the product; therefore, no UK-specific documents have been submitted. The marketing authorisation holder has committed to submit the UK labelling to the regulatory authority for review before marketing the product.