Public Assessment Report

Decentralised Procedure

Paracetamol/Guaifenesin/Phenylephrine Hydrochloride
Wrafton 500 mg/200 mg/10 mg Powder for Oral Solution

(paracetamol, guaifenesin, phenylephrine hydrochloride)

Procedure No: UK/H/5801/001/DC

UK Licence No: PL 12063/0127

Wrafton Laboratories Limited
LAY SUMMARY

Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Wrafton 500 mg/200 mg/10 mg Powder for Oral Solution

(paracetamol 500 mg/sachet, guaifenesin 200 mg/sachet, phenylephrine hydrochloride 10 mg/sachet, powder for oral solution).

This is a summary of the Public Assessment Report (PAR) for Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Wrafton 500 mg/200 mg/10 mg Powder for Oral Solution (PL 12063/0127; UK/H/5801/001/DC). It explains how Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Wrafton 500 mg/200 mg/10 mg Powder for Oral Solution was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Wrafton 500 mg/200 mg/10 mg Powder for Oral Solution.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

The product will be referred to as Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Powder for Oral Solution throughout the remainder of this PAR.

What is this medicine and what is it used for?
This medicine is a ‘hybrid generic medicine’. This means that it is similar to a ‘reference medicine’ containing the same active substances but is available as a powder in individual sachets for reconstitution as a hot drink rather than as an oral liquid.

The company (Wrafton Laboratories Limited) did not have to provide additional own data to demonstrate the safety and efficacy of this medicine regarding this difference from the reference medicine, since this product is a generic hybrid medicine that is administered orally as an aqueous solution and contains the same active substances as the reference medicine.

The reference medicine for this product is Beechams All-in-One (Beecham Group Plc, UK).

This medicine is used for the short term symptomatic relief of colds and flu including aches and pains, headache, blocked nose and sore throat, chills and fever, and for relief from chesty coughs.

How does this medicine work?
This medicine contains:
- paracetamol which is a pain reliever (analgesic) and helps reduce temperature when the patient has a fever
- guaifenesin which is an expectorant to help loosen phlegm
- phenylephrine hydrochloride which is a decongestant to reduce swelling in the passages of the nose to help the patient breathe more easily.

How is this medicine used?
The pharmaceutical form of this medicine is a powder for oral solution. The route of administration of this medicine is oral (by mouth).
Pour the contents of 1 sachet into a standard mug. Fill the mug to below the brim with approximately 250 ml (8 fluid oz.) of hot, but not boiling, water. Stir until dissolved, and allow to cool to a drinkable temperature. Drink all of the yellow solution within 1½ hours.

**Adults, the elderly and children 12 years and over:**
1 sachet every 4 hours, as required. Do not take more than 4 sachets (4 doses) in any 24 hour period.

**Do not give to children under 12 years.**

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Do not exceed the stated dose. If the patient’s symptoms persist for more than 5 days or worsen, they must see a doctor or pharmacist.

The patient must not take more medicine than the label tells them to. If the patient does not get better, they should talk to their doctor.

**The patient must talk to a doctor at once if they take too much of this medicine even if they feel well. This is because too much paracetamol can cause delayed, serious liver damage.** Go to your nearest hospital casualty department. Take this medicine and this leaflet with you.

This medicine can be obtained without a prescription and is available on the general sales list (GSL).

**What benefits of this medicine have been shown in studies?**
No additional studies were needed as this medicine is a hybrid medicine that is administered as an oral solution and contains the same active substances as the reference medicine, Beechams All-in-One (Beecham Group Plc, UK).

**What are the possible side effects of this medicine?**
Most people do not have any side effects while taking this medicine. However, if the patient experiences any of the following side effects, or anything else unusual happens, the patient must stop taking the medicine immediately, and see their doctor or pharmacist.

Common side effects (affecting less than 1 in 10 people but more than 1 in 100 people) are:
- difficulty sleeping (insomnia)
- diarrhoea, nausea (feeling sick)
- nervousness, tremors, irritability, restlessness or excitability
- a rise in blood pressure with headache, dizziness, vomiting (being sick) and irregular heart beat (palpitations).

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet available on the MHRA website.

For the full list of restrictions, see the package leaflet.

**Why was this medicine approved?**
The MHRA decided that this medicine’s benefits are greater than its risks and recommended that it be approved for use.
What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan (RMP) has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for this medicine including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

Other information about this medicine
Czech Republic, Italy, Slovakia and the UK agreed to grant a Marketing Authorisation for this medicine on 27 August 2015. A Marketing Authorisation was granted in the UK on 18 September 2015.

The full PAR for this medicine follows this summary.

For more information about treatment with this medicine, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in November 2015.
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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Member States considered that the application for Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Powder for Oral Solution (PL 12063/0127; UK/H/5801/001/DC) could be approved. The product can be obtained without a prescription and is available on the general sales list (GSL) and is indicated for the short term symptomatic relief of colds and flu including aches and pains, headache, blocked nose and sore throat, chills and fever, and for relief from chesty coughs.

The application was submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS), and Czech Republic, Italy and Slovakia as Concerned Member State (CMS). The application was submitted under Article 10(3) of Directive 2001/83/EC, as amended, as a hybrid application. The reference medicinal product for this application is Beechams All-in-One, which was originally authorised to Beecham Group Plc, UK (PL 00079/0320) on 19 October 1994.

Paracetamol:
The mechanism of analgesic action of paracetamol has not been fully determined. Paracetamol may act predominantly by inhibiting a prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Paracetamol probably produces antipyresis by acting on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

Guaifenesin:
Guaifenesin is a well-known expectorant. Such expectorants are known to increase the volume of secretions in the respiratory tract and therefore to facilitate their removal by ciliary action and coughing.

Phenylephrine hydrochloride:
Sympathomimetic amines, such as phenylephrine, act on alpha-adrenergic receptors of the respiratory tract to produce vasoconstriction, which temporarily reduces the swelling associated with inflammation of the mucous membranes lining the nasal and sinus passages. This allows the free drainage of the sinusoidal fluid from the sinuses.

In addition to reducing mucosal lining swelling, decongestants also suppress the production of mucus, therefore preventing a build-up of fluid within the cavities which could otherwise lead to pressure and pain.

No new non-clinical or clinical data have been submitted and none are required for applications of this type. A bioequivalence study was not necessary to support this application as both test and reference products are aqueous oral solutions at the time of administration.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of this product.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates or satisfactory inspection summary reports as certification that acceptable standards of GMP
are in place at those non-Community sites.

The RMS and CMS considered that the application could be approved at the end of procedure (Day 210) on 27 August 2015. After a subsequent national phase, a licence was granted in the UK on 18 September 2015.
II  QUALITY ASPECTS

II.1  Introduction

Each sachet of powder for oral solution contains 500 mg paracetamol, 200 mg guaifenesin and 10 mg phenylephrine hydrochloride.

Other ingredients consist of the pharmaceutical excipients sucrose, citric acid E330, tartaric acid E334, sodium cyclamate E952, sodium citrate E331, acesulfame potassium E950, aspartame E951, powdered menthol flavour, lemon flavour, lemon juice flavour and quinoline yellow E104. The product is packed into sachets comprised of ionomer (product contact layer)/aluminium foil/low density polyethylene/paper (outer layer) and is available in pack sizes of 5, 6 and 10 sachets. Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2.  Drug Substances

(1)  Paracetamol

INN: Paracetamol
Chemical name: N-(4-hydroxyphenyl)acetamide.

Structural formula:

\[
\begin{align*}
\text{H}_3\text{C} & \text{ } \text{O} \\
& \text{ } \text{\text{NH}} \\
\text{O} & \text{ } \text{\text{OH}} \\
\text{H}_3\text{C} & \text{ } \text{\text{OH}} \\
\end{align*}
\]

Molecular formula: C₈H₉NO₂
Molecular mass: 151.2
Appearance: A white, crystalline powder.
Solubility: Sparingly soluble in water, freely soluble in alcohol and very slightly soluble in dichloromethane.

Paracetamol is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, paracetamol, are covered by the European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

(2)  Guaifenesin

INN: Guaifenesin
Chemical name: (2RS)-3-(2-methoxyphenoxy)propane-1,2-diol.

Structural formula:

\[
\begin{align*}
\text{O} & \text{ } \text{\text{OH}} \\
& \text{ } \text{\text{OH}} \\
\text{OCH}_3 & \text{ } \text{\text{OH}} \\
\text{OCH}_3 & \text{ } \text{\text{OH}} \\
\end{align*}
\]

and enantiomer

Molecular formula: C₁₀H₁₄O₄
Molecular mass: 198.22
Appearance: A white, or almost white, crystalline powder.
Solubility: Sparingly soluble in water and soluble in ethanol.

Guaifenesin is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, guaifenesin, are covered by the European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

(3) Phenylephrine hydrochloride
INN: Phenylephrine hydrochloride
Chemical name: (1R)-1-(3-hydroxyphenyl)-2-(methylamino)ethanol

Structural formula:

\[
\begin{align*}
\text{HO} & \quad \text{N} \quad \text{H} \quad \text{CH}_3, \quad \text{HCl} \\
\end{align*}
\]

Molecular formula: C\textsubscript{9}H\textsubscript{14}ClNO\textsubscript{2}
Molecular mass: 203.7
Appearance: A white or almost white, crystalline powder.
Solubility: Freely soluble in water and in ethanol (96 per cent).

Phenylephrine hydrochloride is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, phenylephrine hydrochloride, are covered by the European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3. Medicinal Product
Pharmaceutical Development
The objective of the development programme was to formulate a safe, efficacious, powder for oral solution containing 500 mg paracetamol, 200 mg guaifenesin and 10 mg phenylephrine hydrochloride per sachet that was a palatable solution when dissolved in about 250 ml of hot (but not boiling) water.

A satisfactory account of the pharmaceutical development has been provided.

All excipients comply with their respective European Pharmacopoeia monographs with the exception of quinoline yellow E104 and the flavourings menthol flavour, lemon flavour and lemon juice flavour which are controlled to suitable in-house specifications. In addition, confirmation has been provided that the menthol flavour, lemon flavour and lemon juice flavour comply with Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and quinoline yellow E104 is in compliance with Directive 2008/128/EC. Satisfactory Certificates of Analysis have been provided for all excipients. Suitable batch analysis data have been provided for each excipient.
None of the excipients contain materials of animal or human origin.

No genetically modified organisms (GMO) have been used in the preparation of this product.

**Manufacture of the product**
A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated at commercial-scale batch size and shown satisfactory results.

**Finished Product Specification**
The finished product specification proposed is acceptable. Test methods have been described that have been adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for all working standards used.

**Stability of the Product**
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 36 months for the unopened sachet with no special storage conditions. The shelf-life of the product after reconstitution is 1.5 hours.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**
There are no objections to the approval of this application from a pharmaceutical viewpoint.

**III NON-CLINICAL ASPECTS**

**III.1 Introduction**
As the pharmacodynamic, pharmacokinetic and toxicological properties of paracetamol, guaifenesin and phenylephrine hydrochloride are well-known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The MAH’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

**III.2 Pharmacology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.3 Pharmacokinetics**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.4 Toxicology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.5 Ecotoxicity/environmental risk assessment (ERA)**
Since Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Powder for Oral Solution is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

**III.6 Discussion on the non-clinical aspects**
No new non-clinical studies were conducted or necessary for this type of application.

There are no objections to the approval of this application from a non-clinical viewpoint.

IV CLINICAL ASPECTS

IV.1 Introduction
As per the guideline on the Investigation of Bioequivalence (CPMP/QWP/EWP/1401/98 Rev. 1/Corr**), “bioequivalence studies are generally not required if the test product is to be administered as an aqueous oral solution containing the same active substance as the currently approved product.”

The formulation proposed for Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Powder for Oral Solution has the same qualitative and quantitative composition in terms of the active substances as the reference product Beechams All-in-One (Beecham Group Plc, UK) and is also administered orally, as an aqueous solution. Therefore, a biowaiver can be justified in accordance with the EU guideline: Investigation of Bioequivalence (CPMP/QWP/EWP/1401/98 Rev. 1/Corr** and no bioequivalence studies are required for this application.

No new efficacy or safety studies have been performed and none are required for this type of application. A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of the active substances.

IV.2 Pharmacokinetics
Refer to section ‘IV.1; Introduction’ detailed above.

IV.3 Pharmacodynamics
Refer to section ‘IV.1; Introduction’ detailed above.

IV.4 Clinical efficacy
No new efficacy data were submitted and none were required for an application of this type.

IV.5 Clinical safety
No new safety data were submitted and none were required for this application.

IV.6 Risk Management Plan (RMP)
The marketing authorisation holder (MAH) has submitted a risk management plan (RMP), in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to paracetamol, guaifenesin and phenylephrine hydrochloride.

A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, are listed below:
Summary table of safety concerns:

| Important identified risks                                                                 | • Hypersensitivity reactions                                                  |
|                                                                                            | • Worsening of hepatic function in patients with hepatic or severe renal impairment |
|                                                                                            | • Use in patients with hypertension or serious heart disease                   |
|                                                                                            | • Severe hyperthyroidism                                                       |
|                                                                                            | • Use in patients with diabetes                                                |
|                                                                                            | • Use in patients who are also taking Monoamine Oxidase Inhibitors (MAOIs) or within 2 weeks of stopping MAOIs |
|                                                                                            | • Use in patients with narrow-angle glaucoma                                    |
|                                                                                            | • Use in patients with urinary retention                                       |
|                                                                                            | • Use in patients who are also taking other sympathomimetic drugs               |
| Important potential risks                                                                 | • Blood dyscrasias (thrombocytopenia, agranulocytosis, haemolytic anaemia, neutropenia, leucopenia and pancytopenia) |
|                                                                                            | • Cardiovascular events (Tachycardia, Palpitations, Hypertension)               |
|                                                                                            | • Use with drugs that induce liver enzymes                                     |

| Missing information | N/A |

Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.

**IV.7 Discussion on the clinical aspects**

No new clinical studies were conducted or necessary for this type of application.

There are no objections to the approval of this application from a clinical viewpoint.

The grant of a marketing authorisation is recommended for this application.

**V User consultation**

The package leaflet has been evaluated via a user consultation study, in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability, as set out in the guideline on the readability of the label and package leaflet of medicinal products for human use.

**VI Overall conclusion, benefit/risk assessment and recommendation**

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with paracetamol, guaifenesin and phenylephrine hydrochloride is considered to have demonstrated the therapeutic value of the compounds. The benefit-risk is, therefore, considered to be positive.
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The following text is the approved label text for this medicine; no label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained:

PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>
[Carton]

1. NAME OF THE MEDICINAL PRODUCT

Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Wrafton 500 mg/200 mg/10 mg Powder for Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each sachet of powder contains the active ingredients: paracetamol 500 mg, guaifenesin 200 mg and phenylephrine hydrochloride 10 mg.

3. LIST OF EXCIPIENTS

Also contains: sucrose, aspartame (E951), sodium citrate and sodium cyclamate (see leaflet for details).

4. PHARMACEUTICAL FORM AND CONTENTS

5. 6 or 10 Sachets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For the short term symptomatic relief of colds and flu including aches and pains, headache, blocked nose and sore throat, chills and fever, and for relief from chesty coughs.

For oral use after dissolving the contents of the sachet in a standard mug of hot, but not boiling water (250 ml). Allow to cool to a drinkable temperature. Drink all of the solution within 1½ hours.

Please read the enclosed leaflet carefully before you take these sachets.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep all medicines out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. Contains paracetamol. Do not take anything else containing paracetamol while taking this medicine. Talk to a doctor at once if you take too much of this medicine even if you feel well.

If you are taking medication or are under medical care, consult your doctor before using this medicine. Do not take with other flu, cold or decongestant products.

8. EXPIRY DATE

EXP: [Date (month and year) will be printed on the carton and embossed on the sachet edge at manufacture] Do not use these sachets after the date shown on the pack.

9. SPECIAL STORAGE CONDITIONS

None
10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

None

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

MA Holder: Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, UK

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 12063/0127

13. **BATCH NUMBER**

BN: (the batch number will be printed embossed on the carton and embossed on the sachet edge at manufacture)

14. **GENERAL CLASSIFICATION FOR SUPPLY**

GSL

15. **INSTRUCTIONS ON USE**

Adults, the elderly and children aged 12 years and over:
One sachet every four hours as required. Do not take more than 4 sachets (4 doses) in any 24 hour period.

Do not give to children under 12 years old.

16. **INFORMATION IN BRAILLE**

Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Wrafton 500 mg/200 mg/10 mg Powder for Oral Solution
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

[Sachet]

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Paracetamol/Guaifenesin/Phenylephrine Hydrochloride Wraflon 500 mg/200 mg/10 mg Powder for Oral Solution

For the short term symptomatic relief of colds and flu including aches and pains, headache, blocked nose and sore throat, chills and fever, and for relief from chesty coughs.

2. METHOD OF ADMINISTRATION

How to take:

For oral use after dissolving the contents of the sachet in a standard mug of hot, but not boiling water (250 ml). Allow to cool to a drinkable temperature. Drink all of the solution within 1½ hours.

Dosage:

Adults, the elderly and children 12 years and over:

One sachet every four hours as required. Do not take more than 4 sachets (4 doses) in any 24 hour period.

Do not give to children under 12 years old.

Do not exceed the stated dose. If symptoms persist for more than 5 days or worsen, consult your doctor.

3. EXPIRY DATE

EXP: [Date (month and year) will be printed on the carton and embossed on the sachet edge at manufacture]

Do not use these sachets after the date shown on the pack.

4. BATCH NUMBER

BN: (the batch number will be printed/embossed on the carton and embossed on the sachet edge at manufacture)

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

4.4g

6. OTHER

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. Contains paracetamol. Do not take anything else containing paracetamol while taking this medicine. Talk to a doctor at once if you take too much of this medicine even if you feel well.

If you are taking medication or are under medical care, consult your doctor before using this medicine. Do not take with other flu, cold or decongestant products.

Ingredients

Each sachet of powder contains the active ingredients: paracetamol 500 mg, guaifenesin 200 mg and phenylephrine hydrochloride 10 mg. Also contains: sucrose, aspartame (E951), sodium citrate and sodium cyclamate (see leaflet for details).

Please read the enclosed leaflet carefully before you take these sachets.

Keep all medicines out of the sight and reach of children.

MA Holder: Wraflon Laboratories Limited, Braunton, Devon, EX33 2DL, UK