Public Assessment Report

Paracetamol and Phenylephrine Max Power Lemon Sachets for Oral Solution
Paracetamol and Phenylephrine Max Power Decongestant Sachets for Oral Solution
Paracetamol and Phenylephrine Max Power Relief Sachets for Oral Solution

Phenylephrine hydrochloride, paracetamol

PL 12063/0083-5

Wrafton Laboratories Ltd

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Lay Summary


These products are for the treatment of the symptoms of cold and flu. The reference product is manufactured by the same company.
Scientific Discussion

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK (MHRA) granted marketing authorisations for the medicinal products Paracetamol and Phenylephrine Max Power Lemon Sachets for Oral Solution (PL 12063/0083), Paracetamol and Phenylephrine Max Power Decongestant Sachets for Oral Solution (PL 12063/0084), Paracetamol and Phenylephrine Max Power Relief Sachets for Oral Solution (PL 12063/0085) on 30/10/2008. These are duplicate products containing the active ingredients paracetamol and phenylephrine hydrochloride and are available on the General Sales List.

These medicinal products are for relief of symptoms of colds and influenza, including the relief of headaches, aches and pains, sore throat, nasal congestion and lowering of temperature. These simple applications were made under article 10c of directive 2001/83/EC.

The reference product is PL 12063/0034-0029, MA Holder is also Wrafton Laboratories LTD, multiple product names provided.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCES

These simple national abridged applications for each of the proposed products were accompanied, in each case, by a satisfactory drug substance specification and confirmation that the drug substances would be supplied from the same supplier as the reference product using the same manufacturing technique. Current EDQM Certificates of Suitability were provided for the drug substances.

DRUG PRODUCT

The drug product specification and a summary of the method of drug product manufacture were provided. The applicant is the manufacturer of the reference product(s). Satisfactory Drug Product Specification was provided based on the European Pharmacopoeia. Satisfactory stability data was provided to support a shelf-life of 3 years with the following storage conditions “Do not store above 25ºC”

Other Ingredients

The other ingredients of the drug products are Sucrose, Sodium citrate, Citric acid, Ascorbic acid, Acesulfame Potassium (E950), Aspartame (E951), Quinoline yellow (E104), Lemon flavours. All excipients met current requirements and none were of human or animal origin.
Summary of Product Characteristics, Patient Information Leaflet and Labels. The SPC, PIL and labels were satisfactory.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY AND ADVICE
A Marketing Authorisation was granted.
Pre-clinical Assessment

No pre-clinical data were provided for these simple applications and none were required.
MEDICAL ASSESSMENT

No clinical data were provided for these simple applications and none were required.
Overall Conclusion and Risk/Benefit Analysis

**Quality**
Satisfactory information on quality was provided demonstrating that the products were the same as the reference product.

**Pre-Clinical**
No pre-clinical data were provided for these simple applications and none were required.

**Clinical**
No clinical data were provided for these simple applications and none were required.

**Risk/Benefit Analysis**
These identical products to the reference product have the same positive risk/benefit.
## Steps Taken During Assessment

<table>
<thead>
<tr>
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<tr>
<td>1</td>
<td>The MHRA received the application on 22/12/2006.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 01/03/2007.</td>
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<tr>
<td>3</td>
<td>Following assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 05/06/2007.</td>
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<td>4</td>
<td>The applicant provided further information in regard to the quality assessment on 28/02/2008.</td>
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<tr>
<td>5</td>
<td>The application was determined on 30/10/2008.</td>
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Steps Taken after Assessment

No non-confidential changes have been made to the market authorisation.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Paracetamol and Phenylephrine Max Power Lemon Sachets Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet contains; 1000 mg Paracetamol, Phenylephrine hydrochloride 12.2 mg.
For full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM
Powder for oral solution.
Yellow powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For relief of symptoms of colds and influenza, including the relief of headaches, aches and pains, sore throat, nasal congestion and lowering of temperature.

4.2 Posology and method of administration
Adults and elderly: For oral administration after dissolution in water. Contents of one sachet dissolved in hot water. May be repeated after 4 – 6 hours. Maximum of 4 sachets in 24 hours.
Children: Not recommended for children under 12 years of age.

4.3 Contraindications
Hypersensitivity to any of the ingredients. Severe coronary heart disease. Hypertension.

4.4 Special warnings and precautions for use
Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Use with caution in patients with Raynaud’s Phenomenon or diabetes.
Contains aspartame (E951) a source of phenylalanine equivalent to 14 mg/dosage unit. May be harmful for people with phenylketonuria. The content of sucrose on a daily basis of four doses is 7.75 g. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

(Label) Immediate medical advice should be sought in the event of an overdose, even if you feel well.
(Leaflet) Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

Do not exceed the stated dose. Do not take with other paracetamol containing products. If symptoms persist consult your doctor. Keep out of the sight and reach of children. If you are pregnant or are being prescribed medicine by your doctor, seek his advice before taking this product.

4.5 Interaction with other medicinal products and other forms of interaction
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. These interactions are considered to be of unlikely clinical significance in acute use at the dosage regimen proposed. Phenylephrine may adversely interact with other sympathomimetics, vasodilators, and β- blockers. Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Not recommended for patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

4.6 Pregnancy and lactation
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding. Phenylephrine hydrochloride: Due to the vasoconstrictive properties of phenylephrine the product should be used with caution in patients with history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
Adverse effects of paracetamol are rare (< 1/1000) but hypersensitivity including skin rash may occur. There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol. Adverse effects of phenylephrine hydrochloride include raised blood pressure, tachycardia and occasionally bradycardia, insomnia, restlessness, tremor and anxiety have occasionally occurred, as have urinary retention and hallucinations.

4.9 Overdose

**Paracetamol**
Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

**Risk factors**
If the patient
a, Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.
Or
b, Regularly consumes ethanol in excess of recommended amounts.
Or
c, Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

**Symptoms**
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

**Management**
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not
a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

Phenylephrine hydrochloride:
Features of severe overdosage of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression. Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an IV α-receptor blocking agent.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
ATC N02BG51
Paracetamol: Paracetamol has both analgesic and antipyretic activity which is believed to be mediated principally through its inhibition of prostaglandin synthesis in the central nervous system.
Phenylephrine hydrochloride: Phenylephrine is a post-synaptic α-receptor agonist with low cardioselective β-receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

5.2 Pharmacokinetic properties
Paracetamol is absorbed rapidly and completely mainly from the small intestine, producing peak plasma levels after 15-20 minutes following oral dosing. The systemic availability is subject to first-pass metabolism and varies with dose between 70% and 90%. The drug is rapidly and widely distributed throughout the body and is eliminated from plasma with a half-life of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (> 80%) which are excreted in the urine.
Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic acid in excess of the body’s needs is eliminated in the urine as metabolites.
Phenylephrine hydrochloride is readily and rapidly absorbed from the gastro-intestinal tract. Presystemic metabolism is high at about 60%, resulting in systemic bioavailability of about 40%. Peak plasma levels occur between 1 and 2 hours and the plasma half-life ranges from 2 – 3 hours. When taken by mouth as a nasal decongestant phenylephrine is usually given at intervals of 4 – 6 hours.

5.3 Preclinical safety data
No preclinical findings of relevance have been reported.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sucrose
Sodium citrate
Citric acid
Ascorbic acid
Acesulfame Potassium (E950)
Aspartame (E951),
Quinoline yellow (E104)
Lemon flavours

6.2 Incompatibilities
None known.

6.3 Shelf life
Three years

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
This product is packed in laminate sachets comprising paper/polyethylene/aluminium foil/ polyethylene.
Five or ten sachets are contained in a boxboard carton.

6.6 Special precautions for disposal
Not applicable.

7 MARKETING AUTHORISATION HOLDER
Perrigo
Wrafton
Braunton
Devon
EX33 2DL.

8 MARKETING AUTHORISATION NUMBER(S)
PL 12063/0083

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
30/10/2008

10 DATE OF REVISION OF THE TEXT
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Paracetamol and Phenylephrine Max Power Decongestant Sachets Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet contains; 1000 mg Paracetamol, Phenylephrine hydrochloride 12.2 mg.
For full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM
Powder for oral solution.
Yellow powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For relief of symptoms of colds and influenza, including the relief of headaches, aches and pains, sore throat, nasal congestion and lowering of temperature.

4.2 Posology and method of administration
Adults and elderly: For oral administration after dissolution in water.
Contents of one sachet dissolved in hot water. May be repeated after 4 – 6 hours.
Maximum of 4 sachets in 24 hours.
Children: Not recommended for children under 12 years of age.

4.3 Contraindications
Hypersensitivity to any of the ingredients.
Severe coronary heart disease. Hypertension.

4.4 Special warnings and precautions for use
Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.
Use with caution in patients with Raynaud’s Phenomenon or diabetes.
Contains aspartame (E951) a source of phenylalanine equivalent to 14 mg/dosage unit. May be harmful for people with phenylketonuria.
The content of sucrose on a daily basis of four doses is 7.75 g. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

(Leaflet) Immediate medical advice should be sought in the event of an overdose, even if you feel well.

(Leaflet) Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

Do not exceed the stated dose. Do not take with other paracetamol containing products. If symptoms persist consult your doctor. Keep out of the sight and reach of children. If you are pregnant or are being prescribed medicine by your doctor, seek his advice before taking this product.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

These interactions are considered to be of unlikely clinical significance in acute use at the dosage regimen proposed.

Phenylephrine may adversely interact with other sympathomimetics, vasodilators, and β- blockers. Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Not recommended for patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

4.6 Pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Phenylephrine hydrochloride: Due to the vasoconstrictive properties of phenylephrine the product should be used with caution in patients with history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects of paracetamol are rare (< 1/1000) but hypersensitivity including skin rash may occur. There have been a few reports of blood
dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol. Adverse effects of phenylephrine hydrochloride include raised blood pressure, tachycardia and occasionally bradycardia, insomnia, restlessness, tremor and anxiety have occasionally occurred, as have urinary retention and hallucinations.

4.9 Overdose

**Paracetamol**
Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

**Risk factors**
If the patient
a. Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.
Or
b. Regularly consumes ethanol in excess of recommended amounts.
Or
c. Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

**Symptoms**
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

**Management**
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas,
outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

Phenylephrine hydrochloride:
Features of severe overdosage of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression. Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an IV α-receptor blocking agent.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC N02BG51

Paracetamol: Paracetamol has both analgesic and antipyretic activity which is believed to be mediated principally through its inhibition of prostaglandin synthesis in the central nervous system.

Phenylephrine hydrochloride: Phenylephrine is a post-synaptic α-receptor agonist with low cardioselective β-receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

5.2 Pharmacokinetic properties

Paracetamol is absorbed rapidly and completely mainly from the small intestine, producing peak plasma levels after 15-20 minutes following oral dosing. The systemic availability is subject to first-pass metabolism and varies with dose between 70% and 90%. The drug is rapidly and widely distributed throughout the body and is eliminated from plasma with a half-life of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (> 80%) which are excreted in the urine.

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic acid in excess of the body’s needs is eliminated in the urine as metabolites. Phenylephrine hydrochloride is readily and rapidly absorbed from the gastro-intestinal tract. Presystemic metabolism is high at about 60%, resulting in systemic bioavailability of about 40%. Peak plasma levels occur between 1 and 2 hours and the plasma half-life ranges from 2 – 3 hours. When taken by mouth as a nasal decongestant phenylephrine is usually given at intervals of 4 – 6 hours.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium citrate
Citric acid
Ascorbic acid
Acesulfame Potassium (E950)
Aspartame (E951),
Quinoline yellow (E104)
Lemon flavours

6.2 Incompatibilities
None known.

6.3 Shelf life
Three years

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
This product is packed in laminate sachets comprising paper/polyethylene/aluminium foil/polyethylene.
Five or ten sachets are contained in a boxboard carton.

6.6 Special precautions for disposal
Not applicable.

7 MARKETING AUTHORITY
Perrigo
Wrafton
Braunton
Devon
EX33 2DL.

8 MARKETING AUTHORITY NUMBER(S)
PL 12063/0084

9 DATE OF FIRST AUTHORITY/RENEWAL OF THE AUTHORITY
30/10/2008

10 DATE OF REVISION OF THE TEXT
SUMMARY OF PRODUCT CHARACTERISTICS

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Paracetamol and Phenylephrine Max Power Relief Sachets Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet contains; 1000 mg Paracetamol, Phenylephrine hydrochloride 12.2 mg.
For full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM
Powder for oral solution.
Yellow powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For relief of symptoms of colds and influenza, including the relief of headaches, aches and pains, sore throat, nasal congestion and lowering of temperature.

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Adults and elderly: For oral administration after dissolution in water. Contents of one sachet dissolved in hot water. May be repeated after 4 – 6 hours.
Maximum of 4 sachets in 24 hours.
Children: Not recommended for children under 12 years of age.

4.3 Contraindications
Hypersensitivity to any of the ingredients.
Severe coronary heart disease. Hypertension.

4.4 Special warnings and precautions for use
Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.
Use with caution in patients with Raynaud’s Phenomenon or diabetes.
Contains aspartame (E951) a source of phenylalanine equivalent to 14 mg/dosage unit. May be harmful for people with phenylketonuria. The content of sucrose on a daily basis of four doses is 7.75 g. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

(Leaflet) Immediate medical advice should be sought in the event of an overdose, even if you feel well.

4.5 Interaction with other medicinal products and other forms of interaction
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. These interactions are considered to be of unlikely clinical significance in acute use at the dosage regimen proposed. Phenylephrine may adversely interact with other sympathomimetics, vasodilators, and \( \beta \)-blockers. Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Not recommended for patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

4.6 Pregnancy and lactation
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding. Phenylephrine hydrochloride: Due to the vasoconstrictive properties of phenylephrine the product should be used with caution in patients with history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
Adverse effects of paracetamol are rare (< 1/1000) but hypersensitivity including skin rash may occur. There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol.

Adverse effects of phenylephrine hydrochloride include raised blood pressure, tachycardia and occasionally bradycardia, insomnia, restlessness, tremor and anxiety have occasionally occurred, as have urinary retention and hallucinations.

### 4.9 Overdose

**Paracetamol**

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

**Risk factors**

If the patient

- a, Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.
- Or
- b, Regularly consumes ethanol in excess of recommended amounts.
- Or
- c, Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

**Symptoms**

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

**Management**

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not
a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

**Phenylephrine hydrochloride:**
Features of severe overdosage of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression. Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an IV $\alpha$-receptor blocking agent.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**ATC N02BG51**

**Paracetamol:** Paracetamol has both analgesic and antipyretic activity which is believed to be mediated principally through its inhibition of prostaglandin synthesis in the central nervous system.

**Phenylephrine hydrochloride:** Phenylephrine is a post-synaptic $\alpha$-receptor agonist with low cardioselective $\beta$-receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

### 5.2 Pharmacokinetic properties

Paracetamol is absorbed rapidly and completely mainly from the small intestine, producing peak plasma levels after 15-20 minutes following oral dosing. The systemic availability is subject to first-pass metabolism and varies with dose between 70% and 90%. The drug is rapidly and widely distributed throughout the body and is eliminated from plasma with a half-life of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (> 80%) which are excreted in the urine.

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic acid in excess of the body’s needs is eliminated in the urine as metabolites.

Phenylephrine hydrochloride is readily and rapidly absorbed from the gastro-intestinal tract. Presystemic metabolism is high at about 60%, resulting in systemic bioavailability of about 40%. Peak plasma levels occur between 1 and 2 hours and the plasma half-life ranges from 2 – 3 hours. When taken by mouth as a nasal decongestant phenylephrine is usually given at intervals of 4 – 6 hours.

### 5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sucrose
Sodium citrate
Citric acid
Ascorbic acid
Acesulfame Potassium (E950)
Aspartame (E951),
Quinoline yellow (E104)
Lemon flavours

6.2 Incompatibilities
None known.

6.3 Shelf life
Three years

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
This product is packed in laminate sachets comprising paper/polyethylene/aluminium foil/ polyethylene. Five or ten sachets are contained in a boxboard carton.

6.6 Special precautions for disposal
Not applicable.

7 MARKETING AUTHORISATION HOLDER
Perrigo
Wrafton
Braunton
Devon
EX33 2DL.

8 MARKETING AUTHORISATION NUMBER(S)
PL 12063/0085

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
30/10/2008

10 DATE OF REVISION OF THE TEXT
Paracetamol and Phenylephrine Max Power
Lemon Sachets Powder for Oral Solution

Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?
This medicine contains:
• paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
• phenylephrine which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily
These ephedrine are used for the relief of the symptoms of colds and flu, including headache, itchiness and pain, sore throat, nasal congestion (blocked nose) and feverishness (high temperature).

2. Is this medicine suitable for you?
Do not take this medicine if you:
• are allergic to paracetamol, phenylephrine or any of the other ingredients
• have a serious heart condition
• have high blood pressure (hypertension).

Please see your doctor or pharmacist before taking this medicine if you:
• are pregnant or breastfeeding
• suffer from kidney or liver problems, including alcoholic liver disease
• have diabetes
• have circulatory disorders such as a condition called Raynaud’s Phenomenon, which results from poor circulation in the fingers and toes
• have an intolerance to some sugars
• suffer with phenylketonuria, a rare, inherited metabolic disorder.

If you are taking any of the following medicines please see your doctor:
• medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colesteartate
• medicines to control feeling sick or being sick such as metoclopramide or domperidone
• medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarines - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
• barbiturates (for sleep aid or to help you sleep), such as phenobarbitone
• tricyclic antidepressants such as imipramine, amitriptyline
• antidepressant drugs called monoamine oxidase inhibitors (MAOIs) or have taken them within the last 14 days - these are medicines such as phenelzine and isocarboxazid
• medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (for example atenolol) or vasodilators (for example hydralazine)
• other decongestant drugs such as ephedrine or xylometazoline.

Contains paracetamol.
Do not take with any other paracetamol-containing products.

Other important information:
Do not drink alcohol (beer, wine, spirits etc) while taking this product.

Please turn over
2. Is this medicine suitable for you?

Information about some of the ingredients in this medicine:
Contains 1,8 g sucrose (sugar) per sachet.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This should be taken into account in patients with diabetes.
Contains aspartame (E951), a source of phenylalanine equivalent to 14 mg per sachet. May be harmful for people with phenylketonuria.
Each sachet contains 18 mg sodium. To be taken into consideration by patients on a controlled sodium diet.

3. How to take this medicine
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.

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. Leave at least 4 to 6 hours between doses. Do not give to children under 12 years.

Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side effects
Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
- allergic reactions such as skin rash
- raised blood pressure
- changes in heart rate
- difficulty sleeping (insomnia)
- restlessness
- tremor
- anxiety
- problems passing water
- hallucinations.

More rarely, the following side effects can happen:
- you may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood.

5. How to store your medicine
Keep all medicines out of the reach and sight of children.
Do not use this medicine after the expiry date printed on the pack. Do not store above 25°C.

6. What is in this medicine?
Each 5 g sachet of yellow powder, taken as a hot lemon drink, contains the active ingredients: paracetamol 1,000 mg and phenylephrine hydrochloride 12.2 mg.
The other ingredients are: sucrose, citric acid, natural lemon flavour, sodium citrate, ascorbic acid (Vitamin C), saccharine sodium (E950) and quinoline yellow (E104).
This product is available in pack sizes of 5 and 10 sachets.

7. Who makes this medicine?
The Marketing Authorisation holder and manufacturer is Parigo, Braunton, Devon, EX33 2DL, UK.
Last revised: September 2007.
PL 12063/0083-5
Paracetamol and Phenylephrine Max Power
Decongestant Sachets Powder for Oral Solution

Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?
This medicine contains:
- paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- phenylephrine which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

These sachets are used for the relief of the symptoms of colds and flu, including headache, aches and pains, sore throat, nasal congestion (blocked nose) and feverishness (high temperature).

2. Is this medicine suitable for you?
Do not take this medicine if you:
- are allergic to paracetamol, phenylephrine or any of the other ingredients
- have a serious heart condition
- have high blood pressure (hypertension).

Please see your doctor or pharmacist before taking this medicine if you:
- are pregnant or breastfeeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have diabetes
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes
- have an intolerance to some sugars
- suffer with phenylketonuria, a rare, inherited metabolic disorder.

If you are taking any of the following medicines please see your doctor:
- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colesterylamine
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- barbiturates for epilepsy or to help you sleep), such as phenobarbitones
- tricyclic antidepressants such as imipramine, amitriptyline
- antidepresant drugs called monoamine oxidase inhibitors (MAOIs) or have taken them within the last 14 days - these are medicines such as phenelzine and isocarboxazid
- medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (for example atenolol) or vasodilators (for example hydralazine)
- other decongestant drugs such as ephedrine or xylometazoline.

Contains paracetamol.
Do not take with any other paracetamol-containing products.

Other important information:
Do not drink alcohol (beer, wine, spirits etc) while taking this product.

Please turn over ➤
2. Is this medicine suitable for you?

Information about some of the ingredients in this medicine:
Contains 1.9 g sucrose (sugar) per sachet.
If you have been told by your doctor that you have
an intolerance to some sugars, contact your doctor
before taking this medicinal product. This should
be taken into account in patients with diabetes.
Contains aspartame (E951), a source of
phenylalanine equivalent to 14 mg per
sachet. May be harmful for people with
phenylketonuria.
Each sachet contains 118 mg sodium.
To be taken into consideration by patients on a
controlled sodium diet.

3. How to take this medicine
Pour the contents of 1 sachet into a standard
mug. Fill the mug to below the brim with
approximately 250ml (8 fluid oz) of hot, but not
boiling, water. Stir until dissolved, and allow to
cool to a drinkable temperature.

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. Leave at least 4 to 6 hours between doses.
Do not give to children under 12 years.
Do not exceed the stated dose. If your
symptoms persist or worsen, you must see a
doctor or pharmacist.

Immediate medical advice should be sought
in the event of an overdose, even if you feel
well, because of the risk of delayed, serious
liver damage. Go to your nearest hospital
casualty department. Take your medicine and this
leaflet with you.

4. Possible side effects
Most people do not have any side effects while
taking this medicine. However, if you experience
any of the following side effects, or anything else
unusual happens, stop taking the medicine
immediately, and see your doctor or pharmacist.

Rare side effects are:
• allergic reactions such as skin rash
• raised blood pressure
• changes in heart rate
• difficulty sleeping (insomnia)
• restlessness
• tremor
• anxiety
• problems passing water
• hallucinations.

More rarely, the following side effects can
happen:
• you may become more prone to bleeding,
bruising, fever and infections, such as sore
throat and ulcers, due to changes in your blood.

5. How to store your medicine
Keep all medicines out of the reach and
sight of children.
Do not use this medicine after the expiry date
printed on the pack. Do not store above 25°C.

6. What is in this medicine?
Each 6 g sachet of yellow powder, taken as a hot lemon
drink, contains the active ingredients: paracetamol
1000 mg and phenylephrine hydrochloride 12.2 mg.
The other ingredients are: sucrose, citric acid,
natural lemon flavours, sodium citrate, ascorbic
acid (Vitamin C), acesulfame potassium (E950),
aspartame (E951) and quinoline yellow (E104).
This product is available in pack sizes of 5 and 10
sachets.

7. Who makes this medicine?
The Marketing Authorisation holder and
manufacturer is Perrigo, Braunton, Devon,
EX33 2DL, UK.
Text revised: September 2007,
PL12063/0084 0000000
Paracetamol and Phenylephrine Max Power
Relief Sachets Powder for Oral Solution
Patient Information Leaflet

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know. This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?
This medicine contains:
- paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- phenylephrine which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.
These sachets are used for the relief of the symptoms of colds and flu, including headache, aches and pains, sore throat, nasal congestion (blocked nose) and feverishness (high temperature).

2. Is this medicine suitable for you?
Do not take this medicine if you:
- are allergic to paracetamol, phenylephrine or any of the other ingredients
- have a serious heart condition
- have high blood pressure (hypertension).
Please see your doctor or pharmacist before taking this medicine if you:
- are pregnant or breastfeeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have diabetes
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes
- have an intolerance to some sugars
- suffer with phenylketonuria, a rare, inherited metabolic disorder.

If you are taking any of the following medicines please see your doctor:
- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarines - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- barbiturates (for epilepsy or to help you sleep), such as phenobarbitone
- tricyclic antidepressants such as imipramine, amitriptyline
- antidepressant drugs called monoamine oxidase inhibitors (MAOIs) or have taken them within the last 14 days - these are medicines such as phenelzine and isocarboxazid
- medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (for example atenolol) or vasodilators (for example hydralazine)
- other decongestant drugs such as ephedrine or xylometazoline.
- Contains paracetamol.
- Do not take with any other paracetamol-containing products.

Other important information:
Do not drink alcohol (beer, wine, spirits etc) while taking this product.

Please turn over ➜
2. Is this medicine suitable for you?
   Information about some of the ingredients in this medicine:
Contains 1.0 g sucrose (sugar) per sachet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This should be taken into account in patients with diabetes.
Contains aspartame (E951), a source of phenylalanine equivalent to 14 mg per sachet. May be harmful for people with phenylketonuria.
Each sachet contains 118 mg sodium. To be taken into consideration by patients on a controlled sodium diet.

3. How to take this medicine
Pour the contents of 1 sachet into a standard mug. Fill the mug to below the rim with approximately 250ml (8 fluid oz) of hot, but not boiling, water. Stir until dissolved and allow to cool to a drinkable temperature.
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. Leave at least 4 to 6 hours between doses.
Do not give to children under 12 years.
Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist.
Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side effects
Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
* allergic reactions such as skin rash
* raised blood pressure
* changes in heart rate
* difficulty sleeping (insomnia)
* restlessness
* tinnitus
* anxiety
* problem passing water
* hallucinations.

More rarely, the following side effects can happen:
* you may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood.

5. How to store your medicine
Keep all medicines out of the reach and sight of children.
Do not use this medicine after the expiry date printed on the pack. Do not store above 25°C.

6. What is in this medicine?
Each 6 g sachet of yellow powder taken as a hot lemon drink, contains the active ingredients: paracetamol 1000 mg and phenylephrine hydrochloride 12.2 mg. The other ingredients are: sucrose, citric acid, natural lemon flavour, sodium citrate, ascorbic acid (Vitamin C), aceasulfame potassium (E950), aspartame (E951) and quinoline yellow (E104). This product is available in pack sizes of 5 and 10 sachets.

7. Who makes this medicine?
The Marketing Authorisation holder and manufacturer is Perrigo, Braunton, Devon, EX33 2DL, UK.
PL 12063/0083-5 0000000
PL 12063/0083-5

Wrafton Laboratories Ltd, Phenylephine and Paracetamol Sachets for Oral Solution

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Paracetamol and Phenylephrine
Max Power Lemon Sachets
Powder for Oral Solution

Helps relieve cold and flu symptoms including fever, headaches, aches and pains, sore throat and blocked nose.

DIRECTIONS FOR USE
For oral use. Pour the contents of one sachet into a mug and fill with hot, but not boiling, water. Stir until dissolved and drink.

DOSAGE
Adults, the elderly and children over 12 years:
Take one sachet every 4 to 6 hours as necessary, up to a maximum of 4 sachets in 24 hours. The powder is taken as a hot lemon drink.

Do not give to children under 12 years.

WARNING
Do not exceed the stated dose.

Contains paracetamol.

Do not take with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Please read the enclosed leaflet carefully before use.

If your symptoms persist or worsen consult your doctor.
Keep out of reach of children. Do not store above 25°C.

INGREDIENTS
Each 5 g sachet of powder for oral solution provides a single dose containing the active ingredients: paracetamol 3000 mg and phenylephrine hydrochloride 12.2 mg. Also contains: xanthine, suspanser (E371), saccharin (see leaflet for more information).

M.A. Holder, Peterborough, Devon EX5 2OL, PL 12063/0083
DIRECTIONS FOR USE:
For oral use. Pour the contents of one sachet into a cup and add water or a suitable liquid to make a drinkable solution.

DOSEAGE:
Adults and children over 12 years: Take one sachet every 4 to 6 hours as necessary. Do not exceed 4 sachets in 24 hours. The provider of care can advise on the amount to use.

Children under 12 years: Do not give to children under 12 years.

WARNINGS:
Do not exceed the stated dose.
Contains paracetamol.

Do not take with any other paracetamol/containing products. Reduction in dose is essential in elderly or debilitated patients, in patients undergoing an operation, or in the event of an overdose, even if you feel well.

Always read the product label carefully before use.

If your symptoms persist, consult your doctor.

Keep out of reach and sight of children.

Do not use above 65 years.

INGREDIENTS:
Each sachet provides a single dose of paracetamol. The active ingredients are paracetamol and phenylephrine hydrochloride. Each sachet also contains: sodium chloride, potassium chloride, sodium bicarbonate, and citric acid. Paracetamol provides analgesic and antipyretic effects. Phenylephrine hydrochloride provides decongestant effects.

For more information, visit www.paracetamol.co.uk or contact your healthcare provider.
PL 12063/0083-5

DIRECTIONS FOR USE
For oral use. Pour the contents of one sachet into a mug and fill with hot, but not boiling, water. Stir until dissolved and drink.

DOSAGE
Adults, the elderly and children over 12 years:
Take one sachet every 4 to 6 hours as necessary, up to a maximum of 4 sachets in 24 hours. The powder is taken as a hot lemon drink.
Do not give to children under 12 years.

WARNINGS
Do not exceed the stated dose.
Contains paracetamol:
Do not take with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose even if you feel well.
Please read the enclosed leaflet carefully before use.
If your symptoms persist or worsen consult your doctor.
Keep all medicines out of the reach and sight of children.
Do not store above 25°C.

INGREDIENTS
Each 5 g sachet of powder for oral solution provides a single dose containing the active ingredients: paracetamol 1000 mg and phenylephrine hydrochloride 15.5 mg. Also contains sucrose, sodium metabisulphite (E223), sodium chloride (E508). For more information, see leaflet issued by the manufacturer.

Wrafton Laboratories Ltd, Phenylephrine and Paracetamol Sachets for Oral Solution