PARACETAMOL 120MG/5ML ORAL SUSPENSION

PL 00427/0140

UKPAR

TABLE OF CONTENTS

PARACETAMOL 120MG/5ML ORAL SUSPENSION

PL 00427/0140

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Rosemont Pharmaceuticals Limited a Marketing Authorisation (licence) for the medicinal product Paracetamol 120mg/5ml Oral Suspension (PL 00427/0140) on 7th March 2007. This is a P licensed medicine available from pharmacies.

Paracetamol 120mg/5ml Oral Suspension contains the active ingredient paracetamol, which is an analgesic (relieves pain) and an antipyretic (lowers your temperature when you have a fever). Paracetamol 120mg/5ml Oral Suspension is used to treat mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, and aches and pains. It may also be given to bring down fever and to help relieve the symptoms of cold and flu.

This application is a duplicate of a previously granted application for Paldesic Paracetamol Suspension 120mg/5ml (PL 00427/0077), held by Rosemont Pharmaceuticals Limited. The test and reference product are identical.

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of taking Paracetamol 120mg/5ml Oral Suspension outweigh the risk; hence a Marketing Authorisation has been granted.

PARACETAMOL 120MG/5ML ORAL SUSPENSION

PL 00427/0140

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Paracetamol 120mg/5ml Oral Suspension (PL 00427/0140) on 7th March 2007. This is a P licensed medicine available from pharmacies.

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended), cross-referring to Paldesic Paracetamol Suspension 120mg/5ml (PL 00427/0077), approved on 21st October 1986.

No new data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.

Paracetamol 120mg/5ml Oral Suspension contains the active ingredient paracetamol, which is an analgesic (relieves pain) and an antipyretic (lowers your temperature when you have a fever). Paracetamol 120mg/5ml Oral Suspension is used to treat mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, and aches and pains. It may also be given to bring down fever and to help relieve the symptoms of cold and flu.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 00427/0140
PROPRIETARY NAME:	Paracetamol 120mg/5ml Oral Suspension
ACTIVE INGREDIENTS:	Paracetamol
COMPANY NAME:	Rosemont Pharmaceuticals Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	P

1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Paracetamol 120mg/5ml Oral Suspension. The proposed MA holder is 'Rosemont Pharmaceuticals Limited, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, West Yorkshire LS11 9XE'.

The reference product is Paldesic Paracetamol Suspension 120mg/5ml (PL 00427/0077), held by Rosemont Pharmaceuticals Limited. The test and reference product are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Paracetamol 120mg/5ml Oral Suspension. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains the active ingredient paracetamol. Each 5ml of suspension contains 120mg of paracetamol. The container closure system is amber type III glass bottles, of size 60ml, 100ml, 125ml, 500ml, or 1000ml. The bottles are closed with a child resistant and tamper-evident high density polypropylene cap, a tamper-evident high density polypropylene cap, or a tamper-evident aluminium cap. The MAH have stated that not all pack sizes will be marketed.

The proposed shelf-life (2 years) and storage conditions (Store below 25^{o}C; Keep the bottle in the outer carton) are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is a P licensed medicine available by supply through pharmacies.

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is 'Rosemont Pharmaceuticals Limited, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, West Yorkshire LS11 9XE'.

The QP responsible for pharmacovigilance is stated and their CV is included.

2.5 Manufacturers

The proposed manufacturing site is consistent with that registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

No materials of animal or human origin are included in the product.

3. EXPERT REPORTS

Satisfactory expert reports and curriculum vitae of experts are provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

PIL

The patient information leaflet has been prepared in line with the details registered for the cross-reference product. The approved PIL is satisfactory.

Carton and bottle label

The approved artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The grounds for this application are considered adequate. It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

As this is a duplicate application for PL 00427/0077, no new clinical data have been supplied with the application and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Medicinal products containing paracetamol have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

Paracetamol is a well known drug and has been used as an analgesic and anti-pyretic agent for many years. This application is identical to the previously granted application for Paldesic Paracetamol Suspension 120mg/5ml (PL 00427/0077).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with paracetamol is considered to have demonstrated the therapeutic value of the compound. The risk: benefit is therefore considered to be positive.

PARACETAMOL 120MG/5ML ORAL SUSPENSION

PL 00427/0140

STEPS TAKEN FOR ASSESMENT

1 The MHRA received the marketing authorisation application on 22nd April 2005

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 12th May 2005

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 5th July 2005

4 The applicant responded to the MHRA's requests, providing further information for the quality sections on 24th November 2005

5 Following assessment of the response the MHRA requested further information relating to the quality sections on 27th January 2006

6 The applicant responded to the MHRA's request, providing further information for the quality sections on 7th February 2006

7 Following assessment of the response the MHRA requested further information relating to the quality sections on 5th April 2006

8 The applicant responded to the MHRA's request, providing further information for the quality sections on 8th August 2006

9 The application was determined on 7th March 2007

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SPC) for Paracetamol 120mg/5ml Oral Suspension is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 120mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol 120mg/5ml

3 PHARMACEUTICAL FORM

Oral Suspension

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For oral administration only

Recommended doses:

		120mg/5ml
CHILDREN	3 - 12 months	2.5 - 5ml
	1 - 5 years	5 - 10ml
	6 - 12 years	10 - 20ml

These doses may be repeated every 4 - 6 hours when necessary with a maximum of 4 doses in 24 hours.

Adults and children over 12: 20 - 40ml every 4 - 6 hours to a maximum of 4g daily.

If pyrexia develops after immunisation, a child can be given a dose of Paracetamol followed, if necessary, by a second dose 4 - 6 hours later. The dose of Paracetamol for post immunisation pyrexia in an infant aged 2 - 3 months is 60mg (2.5ml of the 120mg/5ml presentation); an oral syringe can be obtained from any Pharmacy to give the small dose volume required. The parents should be warned that if the pyrexia persists after the second dose medical advice should be sought.

4.3 CONTRAINDICATIONS

Hypersensitivity to paracetamol and/or other constituents.
Patients with severe hepatic dysfunction.

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 hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Do not give with any other paracetamol-containing products.
Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed serious liver damage.

Do not exceed the recommended dose.
If symptoms persist consult your doctor.
Keep out of the reach and sight of children.

Excipients in the formulation
This product contains parahydroxybenzoates. These may cause allergic reactions (possibly delayed). The product also contains sucrose (3g per 5ml dose) and sorbitol. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

The hepatotoxicity of paracetamol, particularly after overdosage, may be increased by drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants and alcohol.

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 use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Antivirals: Regular use of paracetamol possibly reduces metabolism of zidovudine (increased risk of neutropenia).

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 clinically significant quantities. Available published data do not contraindicate breast feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None.

4.8 UNDESIRABLE EFFECTS

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Cases of acute pancreatitis have been reported. Paracetamol has been widely used and reports of adverse reactions are rare, and are generally associated with overdosage.

Allergic reactions occur occasionally.

Nephrotoxic effects are uncommon and have not been reported in association with therapeutic doses, except after prolonged administration

4.9 OVERDOSE

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, phenobarbital, 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 depleted 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting 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 centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 PHARMACOKINETIC PROPERTIES

Oral absorption is rapid and almost complete, it may be decreased if paracetamol is taken following a high carbohydrate meal.

There is no significant protein binding with doses producing plasma concentrations of below 60mcg (µg)/ml, but may reach moderate levels with high or toxic doses.

Approximately 90 - 95% of a dose is metabolised in the liver, primarily by conjugation with glucuronic acid, sulphuric acid and cysteine. An intermediate metabolite, which may accumulate in overdosage after primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic.

Half life is 1 to 4 hours; does not change with renal failure but may be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly, and in the neonate; may be somewhat shortened in children.

Time to peak concentration, 0.5 - 2 hours; peak plasma concentrations, 5 - 20mcg (µg)/ml (with doses up to 650mg); time to peak effect, 1- 3 hours; duration of action, 3- 4 hours.

Elimination is by the renal route, as metabolites, primarily conjugates, 3% of a dose may be excreted unchanged.

Peak concentration of 10 - 15mcg(µg)/ml have been measured in breast milk, 1 - 2 hours following maternal ingestion of a single 650mg dose. Half life in breast milk is 1.35 - 3.5 hours.

5.3 PRECLINICAL SAFETY DATA
None stated

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS
Propylene glycol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, xanthan gum, sorbitol liquid non-crystallising, sucrose, mango flavour 545329E and purified water

6.2 INCOMPATIBILITIES
None stated.

6.3 SHELF LIFE
24 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store below 25°C. Keep the bottle in the outer carton.

6.5 NATURE AND CONTENTS OF CONTAINER
Amber (Type III) glass bottle with capacity of 60ml, 100ml, 125ml, 500ml and 1000ml.
Closure:
1. Aluminium, wadded, roll-on, pilfer proof closure.
2. HDPE, child resistant, tamper evident, EPE wadded closure
3. HDPE, tamper evident, EPE wadded closure.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
None

7 MARKETING AUTHORISATION HOLDER
Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 00427/0140

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
07/03/2007

10 DATE OF REVISION OF THE TEXT
07/03/2007

11 DOSIMETRY (IF APPLICABLE)
Not applicable.

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not applicable

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET

PARACETAMOL 120MG/5ML ORAL SUSPENSION

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Pharmacode

In this leaflet:

Paracetamol 120mg/5ml Oral Suspension

- The active substance is Paracetamol.
- The other ingredients are methyl and propyl parahydroxybenzoate (E218 and E216), propylene glycol (E1520), xanthan gum (E415), sorbitol liquid 70% (E420), sucrose, mango flavour (containing propylene glycol and isopropyl alcohol) and purified water.

Marketing Authorisation Holder and Manufacturer:
Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

1. WHAT PARACETAMOL 120mg/5ml ORAL SUSPENSION IS AND WHAT IT IS USED FOR

It is a white to off-white oral suspension with odour of mango.
It is provided in an amber glass bottle containing 100ml or 500ml of suspension.
It contains paracetamol that belongs to a group of medicines called analgesics that help to ease pain.
Paracetamol is used to treat mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains. It may also have been given to help reduce a fever and to help relieve the symptoms of cold and flu.

2. BEFORE YOU TAKE PARACETAMOL 120mg/5ml ORAL SUSPENSION

Do not take this medicine but speak to your doctor if:
- you have ever had an unusual reaction to paracetamol or any of the ingredients listed
- you have a liver disorder

Take special care with this medicine:

You must speak to the doctor if:
- you have a kidney disorder
- you are dependent on alcohol

If you drink large amounts of alcohol, you may be more susceptible to the side effects of paracetamol.

Pregnancy and Breast-feeding:

You must ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines:
This medicine should not affect you ability to drive or use machines.

Important information about some of the ingredients of this medicine:

This medicine contains parahydroxybenzoates (preservatives) which may cause allergic reactions, possibly delayed.
The medicine also contains 3g of sucrose in each 5ml. This should be taken into account if you have diabetes mellitus.
It also contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Inform your doctor if you are taking any of the following:

- barbiturates (sleeping tablets)
- tricyclic antidepressants (e.g. amitriptyline)
- colestyramine (used in the treatment of high cholesterol levels)
- warfarin (used to thin the blood and prevent clotting)
- zidovudine (used in HIV infections and AIDS)
- domperidone and metoclopramide (used in the treatment of nausea and vomiting)

DO NOT GIVE WITH ANY OTHER PARACETAMOL-CONTAINING PRODUCTS

3. HOW TO TAKE PARACETAMOL 120mg/5ml ORAL SUSPENSION

This medicine is only to be taken via the mouth.

Shake the bottle well before use.

Children	3 -12 months:	2.5 to 5ml
Children	1-5 years:	5 to 10ml
Children	6- 12 years:	10 to 20ml
Adults and children over 12:		20 to 40ml (up to a maximum of 4g daily).

Dosage for children under 3 months is at the physician's discretion. In the case of febrile response (fever) following vaccination at 2 months, a 2.5ml dose is suitable.

This dose may be repeated every 4-6 hours, when necessary but not more than 4 doses in 24 hours.
Do not exceed the stated dose.

If symptoms persist for more than 3 days consult your doctor.

4. POSSIBLE SIDE EFFECTS

Immediate medical advice should be sought in the event of an overdose even if the child seems well because of the risk of delayed, serious liver damage.

There may be no symptoms during the first 24 hours although pallor, nausea and vomiting and abdominal pain may occur.

Along with its desired effect, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do they may need medical attention.

These may be:

Skin rashes, blood disorders (these may be seen as fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruises) and inflammation of the pancreas (this may be seen as severe pain in the abdomen and back, fever, loss of appetite, nausea and vomiting).

If paracetamol is taken for a long time, it may lead to kidney problems.

Allergic reactions may also occur. The symptoms that may be seen are a rash and swelling and in severe cases difficulty in breathing.

If you notice any side effects not mentioned in this leaflet or you are worried about a symptom you have, please inform your doctor or pharmacist.

5. STORING PARACETAMOL 120mg/5ml ORAL SUSPENSION

Keep out of the reach and sight of children.

Paracetamol Oral Suspension should be stored below 25°C and protected from light.

The label on the bottle shows an expiry date (month, year). Do not use this product after this date.
Do not keep outdated medicine or medicine that is no longer wanted. Take it to your pharmacist for safe disposal.

Always keep the medicine in the bottle in which it was originally given to you.

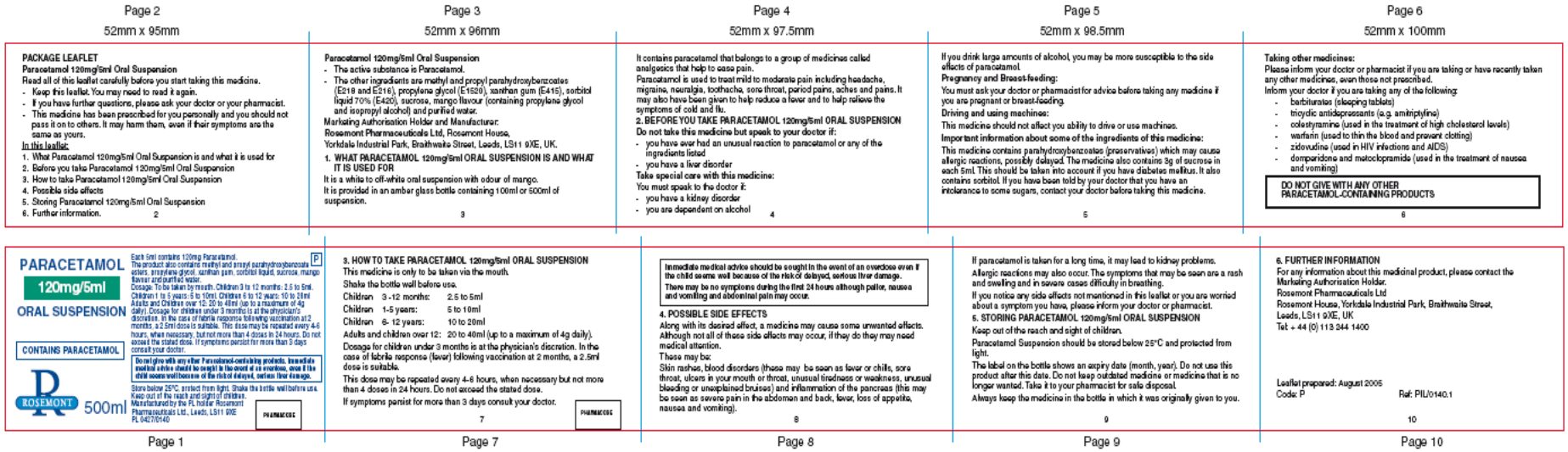
6. FURTHER INFORMATION

For any information about this medicinal product, please contact the Marketing Authorisation Holder.
Rosemont Pharmaceuticals Ltd
Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK

Tel: + 44 (0) 113 244 1400

Leaflet prepared: August 2005

Leaflet for bottle size 500ml



Page 2
52mm x 95mm

PACKAGE LEAFLET
Paracetamol 120mg/5ml Oral Suspension
Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

2

Page 3
52mm x 96mm

Paracetamol 120mg/5ml Oral Suspension
- The active substance is Paracetamol.
- The other ingredients are methyl and propyl parahydroxybenzoates (E218 and E216), propylene glycol (E1520), xanthan gum (E415), sorbitol liquid 70% (E420), sucrose, mango flavour (containing propylene glycol and isopropyl alcohol) and purified water.

Marketing Authorisation Holder and Manufacturer:
Rosemont Pharmaceuticals Ltd, Rosemont House,
Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

1. WHAT PARACETAMOL 120mg/5ml ORAL SUSPENSION IS AND WHAT IT IS USED FOR
It is a white to off-white oral suspension with odour of mango.
It is provided in an amber glass bottle containing 100ml or 500ml of suspension.
3

Page 4
52mm x 97.5mm

It contains paracetamol that belongs to a group of medicines called analgesics that help to ease pain.
Paracetamol is used to treat mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains. It may also have been given to help reduce a fever and to help relieve the symptoms of cold and flu.

2. BEFORE YOU TAKE PARACETAMOL 120mg/5ml ORAL SUSPENSION
Do not take this medicine but speak to your doctor if:
- you have ever had an unusual reaction to paracetamol or any of the ingredients listed
- you have a liver disorder

Take special care with this medicine:
You must speak to the doctor if:
- you have a kidney disorder
- you are dependent on alcohol
4

Page 5
52mm x 98.5mm

If you drink large amounts of alcohol, you may be more susceptible to the side effects of paracetamol.
Pregnancy and Breast-feeding:
You must ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.
Driving and using machines:
This medicine should not affect you ability to drive or use machines.
Important information about some of the ingredients of this medicine:
This medicine contains parahydroxybenzoates (preservatives) which may cause allergic reactions, possibly delayed. The medicine also contains 3g of sucrose in each 5ml. This should be taken into account if you have diabetes mellitus. It also contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
5

Page 6
52mm x 100mm

Taking other medicines:
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.
Inform your doctor if you are taking any of the following:
- barbiturates (sleeping tablets)
- tricyclic antidepressants (e.g. amitriptyline)
- colestyramine (used in the treatment of high cholesterol levels)
- warfarin (used to thin the blood and prevent clotting)
- zidovudine (used in HIV infections and AIDS)
- domperidone and metoclopramide (used in the treatment of nausea and vomiting)

DO NOT GIVE WITH ANY OTHER PARACETAMOL-CONTAINING PRODUCTS
6

PARACETAMOL
120mg/5ml
ORAL SUSPENSION
CONTAINS PARACETAMOL
ROSEMONT
500ml

Each 5ml contains 120mg Paracetamol.
The product also contains methyl and propyl parahydroxybenzoate esters, propylene glycol, xanthan gum, sorbitol liquid, sucrose, mango flavour and purified water.
Dosage: To be taken by mouth. Children 3 to 12 months: 2.5 to 5ml. Children 1 to 5 years: 5 to 10ml. Children 6 to 12 years: 10 to 20ml Adults and Children over 12: 20 to 40ml (up to a maximum of 4g daily). Dosage for children under 3 months is at the physician's discretion. In the case of febrile response following vaccination at 2 months, a 2.5ml dose is suitable. This dose may be repeated every 4-6 hours, when necessary, but not more than 4 doses in 24 hours. Do not exceed the stated dose. If symptoms persist for more than 3 days consult your doctor.
Do not give with any other Paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if the child seems well because of the risk of delayed, serious liver damage.
Store below 25°C, protect from light. Shake the bottle well before use. Keep out of the reach and sight of children.
Manufactured by the PL holder Rosemont Pharmaceuticals Ltd., Leeds, LS11 9XE
PL 04270/0140
PHARMACODE
Page 1

3. HOW TO TAKE PARACETAMOL 120mg/5ml ORAL SUSPENSION
This medicine is only to be taken via the mouth.
Shake the bottle well before use.

Children	3 -12 months:	2.5 to 5ml
Children	1-5 years:	5 to 10ml
Children	6- 12 years:	10 to 20ml
Adults and children over 12:		20 to 40ml (up to a maximum of 4g daily).

Dosage for children under 3 months is at the physician's discretion. In the case of febrile response (fever) following vaccination at 2 months, a 2.5ml dose is suitable.
This dose may be repeated every 4-6 hours, when necessary but not more than 4 doses in 24 hours. Do not exceed the stated dose.
If symptoms persist for more than 3 days consult your doctor.
PHARMACODE
7

Immediate medical advice should be sought in the event of an overdose even if the child seems well because of the risk of delayed, serious liver damage.
There may be no symptoms during the first 24 hours although pallor, nausea and vomiting and abdominal pain may occur.

4. POSSIBLE SIDE EFFECTS
Along with its desired effect, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do they may need medical attention.
These may be:
Skin rashes, blood disorders (these may be seen as fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruises) and inflammation of the pancreas (this may be seen as severe pain in the abdomen and back, fever, loss of appetite, nausea and vomiting).
8

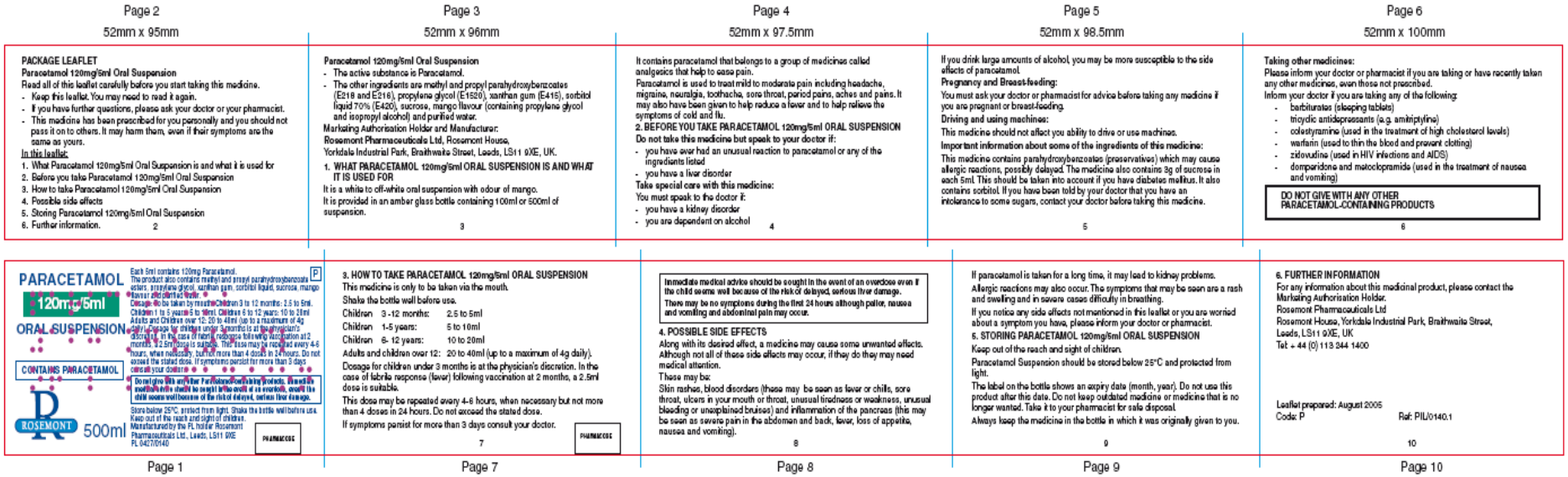
If paracetamol is taken for a long time, it may lead to kidney problems.
Allergic reactions may also occur. The symptoms that may be seen are a rash and swelling and in severe cases difficulty in breathing.
If you notice any side effects not mentioned in this leaflet or you are worried about a symptom you have, please inform your doctor or pharmacist.

5. STORING PARACETAMOL 120mg/5ml ORAL SUSPENSION
Keep out of the reach and sight of children.
Paracetamol Suspension should be stored below 25°C and protected from light.
The label on the bottle shows an expiry date (month, year). Do not use this product after this date. Do not keep outdated medicine or medicine that is no longer wanted. Take it to your pharmacist for safe disposal.
Always keep the medicine in the bottle in which it was originally given to you.
9

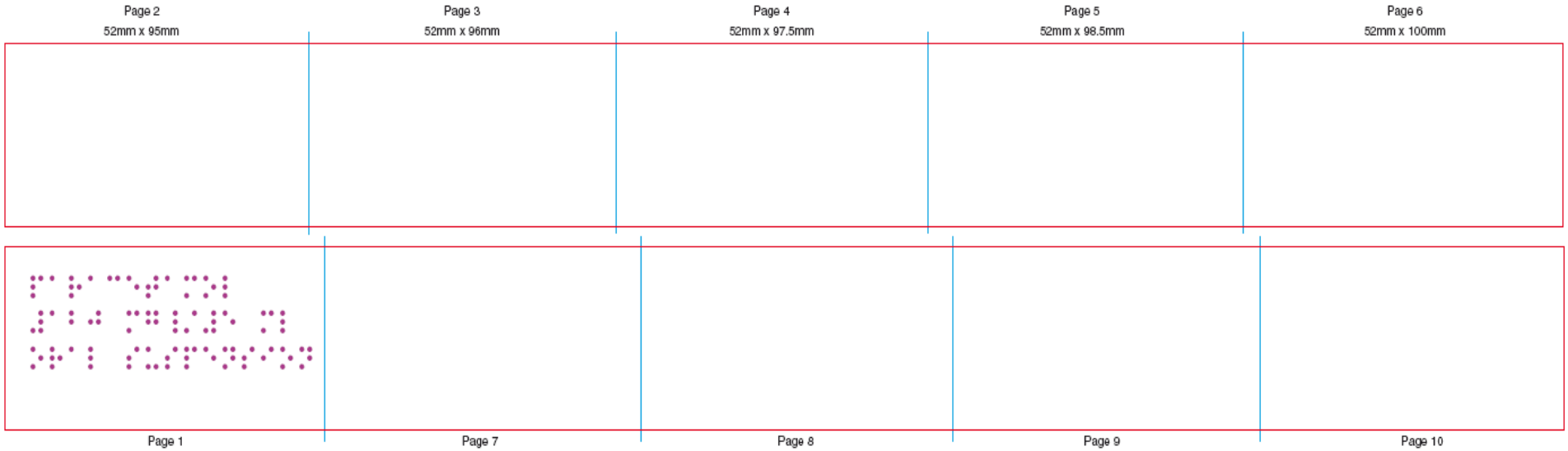
6. FURTHER INFORMATION
For any information about this medicinal product, please contact the Marketing Authorisation Holder.
Rosemont Pharmaceuticals Ltd
Rosemont House, Yorkdale Industrial Park, Braithwaite Street,
Leeds, LS11 9XE, UK
Tel: + 44 (0) 113 244 1400

Leaflet prepared: August 2005
Code: P
Ref: PIL/0140.1
10

Leaflet for bottle size 500ml, with Braille



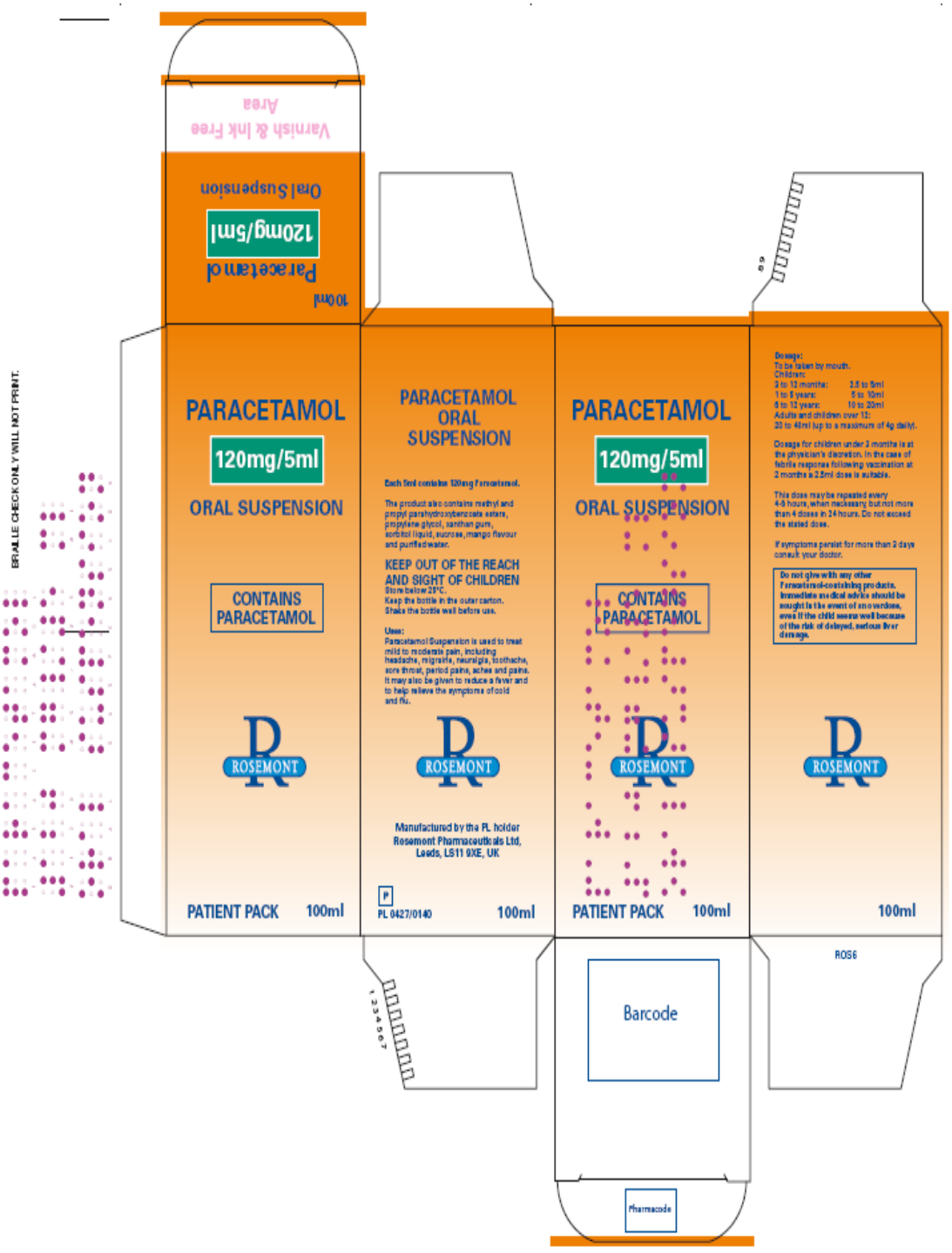
Leaflet for bottle size 500ml showing braille only



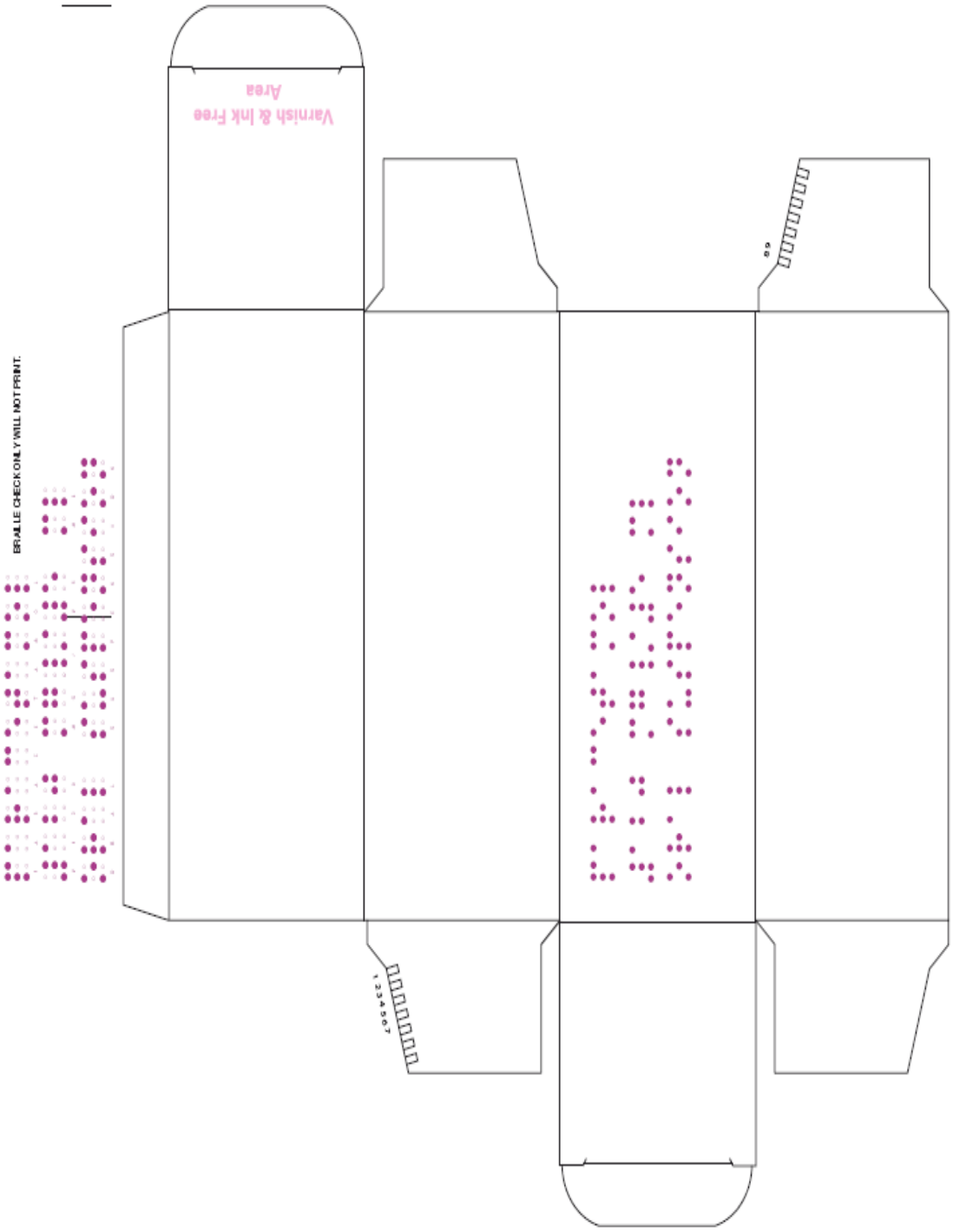
CARTON

Bottle size 100ml

Carton for bottle size 100ml, with braille

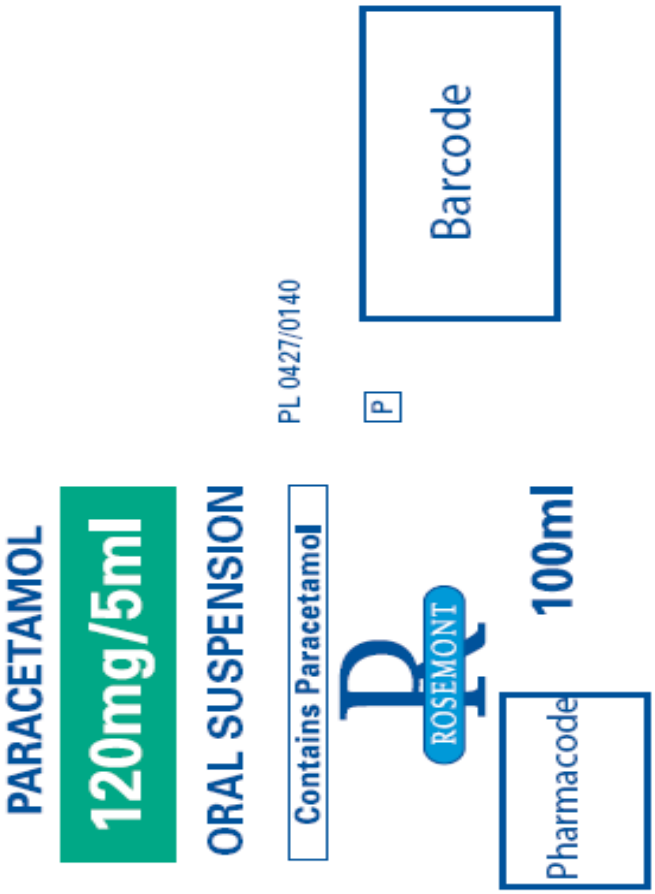


Carton showing braille only



LABELLING

Bottle size 100ml label



Each 5ml contains 120mg Paracetamol.
The product also contains methyl and propyl parahydroxybenzoate esters, propylene glycol, xanthan gum, sorbitol liquid, sucrose, mango flavour and purified water.
Dosage: To be taken by mouth.

Children 3 to 12 months	2.5 to 5ml
Children 1 to 5 years	5 to 10ml
Children 6 to 12 years	10 to 20ml

Adults and Children over 12: 20 to 40ml (up to a maximum of 4g daily)
Dosage for children under 3 months is at the physician's discretion. In the case of febrile response following vaccination at 2 months, a 2.5ml dose is suitable.
This dose may be repeated every 4-6 hours, when necessary, but not more than 4 doses in 24 hours. Do not exceed the stated dose.
If symptoms persist for more than 3 days consult your doctor.

Do not give with any other Paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if the child seems well because of the risk of delayed, serious liver damage.

Store below 25°C. Keep the bottle in the outer carton.
Shake the bottle well before use.
Keep out of the reach and sight of children.

Manufactured by the PL holder
Rosemont Pharmaceuticals Ltd, Leeds, LS11 9XE, UK.

Bottle size 500ml label