

PARACETAMOL 500MG CAPSULES

(paracetamol)

PL 31308/0004-6

UK Public Assessment Report

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PARACETAMOL 500MG CAPSULES**(paracetamol)****PL 31308/0004-6****LAY SUMMARY**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Max Remedies Limited Marketing Authorisations (licences) for the medicinal product Paracetamol 500mg Capsules (PL 31308/0004-6) on 16th December 2009.

The products are available in numerous pack sizes. Pack sizes of up to and including 16 capsules are available on the General Sales List (GSL), and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist. Pack sizes of up to and including 32 capsules are P licensed medicines available only from pharmacies, under the supervision of a pharmacist. Pack sizes greater than 32 capsules are classified as prescription-only medicines (POM).

Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers your temperature when you have a fever). Paracetamol 500mg Capsules are used to relieve headache, migraine, rheumatic or muscular pain, backache, neuralgia, toothache, period pain and the symptoms of colds and flu.

These applications are duplicates of a previously granted application for Boots Paracetamol Capsules 500mg (PL 00014/0442), held by The Boots Company plc. The test and reference products are identical.

No new or unexpected safety concerns arose from these simple applications and it was therefore judged that the benefits of taking Paracetamol 500mg Capsules outweigh the risks; hence Marketing Authorisations have been granted.

PARACETAMOL 500MG CAPSULES

(paracetamol)

PL 31308/0004-6

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Max Remedies Limited Marketing Authorisations (MAs) for the medicinal product Paracetamol 500mg Capsules (PL 31308/0004-6) on 16th December 2009. This product is indicated for the relief of headaches, migraine, rheumatic, muscular and back pain, neuralgia, toothache and period pain, and to relieve the symptoms of colds and flu.

The applications were submitted as simple abridged 'informed consent' applications according to article 10c of Directive 2001/83/EC (as amended), cross-referring to Boots Paracetamol Capsules 500mg (PL 00014/0442), held by The Boots Company plc, and approved on 15th September 1992.

The products are available in numerous pack sizes. Pack sizes of up to and including 16 capsules are classified as GSL; pack sizes of up to and including 32 capsules are P licensed; pack sizes of greater than 32 capsules are prescription-only medicines (POM).

Paracetamol is a peripherally acting analgesic with antipyretic activity. Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependent.

No new data were submitted nor was it necessary for these simple applications, as the data are 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.

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

The marketing authorisation holder has provided adequate justification for not submitting a Risk Management Plan (RMP) and Environmental Risk Assessment (ERA).

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 31308/0004-6
PROPRIETARY NAME:	Paracetamol 500mg Capsules
ACTIVE INGREDIENT/S:	Paracetamol
COMPANY NAME:	Max Remedies Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	GSL / P / POM – depending on pack size

1. INTRODUCTION

These are simple abridged applications, submitted under Article 10c of Directive 2001/83/EC (as amended) for Paracetamol 500mg Capsules. The proposed MA holder is 'Max Remedies Ltd, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire, HD9 2JT'.

The reference product is Boots Paracetamol Capsules 500mg (PL 00014/0442), held by The Boots Company plc. The test and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Paracetamol 500mg Capsules. The product has been named in line with current requirements.

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

The capsules are marketed in PVC-PVdC-Glassine paper-aluminium foil blister strips, which are packaged with the Patient Information Leaflet (PIL) into cardboard outer cartons in pack sizes of 6, 8, 10, 12, and 16 capsules (for PL 31308/0004); 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, and 32 capsules (for PL 31308/0005); and 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, 32, 36, 48, and 96 capsules (for PL 31308/0006). The MAH has stated that not all pack sizes will be marketed.

The proposed shelf-life (36 months) and storage conditions (Do not store above 30°C; Store in the original package) are consistent with the details registered for the cross-reference product.

2.3 Legal status

Pack sizes of up to and including 16 capsules are available on the General Sales List (GSL), and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Pack sizes of up to and including 32 capsules are P licensed medicines available only from pharmacies, under the supervision of a pharmacist.

Pack sizes of more than 32 capsules are prescription-only medicines (POM).

2.4 Marketing authorisation holder / Contact Persons / Company

The proposed Marketing Authorisation holder is 'Max Remedies Ltd, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire, HD9 2JT'.

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

The magnesium stearate is of vegetable origin. The only excipient used that contains material of animal or human origin is gelatin. Certificates of Suitability have been provided by all the gelatine suppliers stating that the gelatine they provide meets the criteria described in the current version of the monograph 'Products with risk of transmitting agents of animal spongiform encephalopathies'.

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 (white and blue hard capsules with no markings) is consistent with that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The approved SmPCs are consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

PIL

The patient information leaflets have been prepared in the user tested format and in line with the details registered for the cross-reference product. The approved PILs are satisfactory.

Carton and bottle label

Colour mock-ups of the labelling have been provided and are satisfactory. The approved artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. The applicant has included the name of the product in Braille on the outer packaging. For the POM packs, the carton includes sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The grounds for these applications are considered adequate. Marketing Authorisations were, therefore, granted.

PRECLINICAL ASSESSMENT

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

No new preclinical data have been supplied with these applications and none are required for applications of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

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

As these are duplicate applications for PL 00014/0442, no new clinical data have been supplied with the applications and none are required. A clinical expert report has been written by a suitably qualified person and is satisfactory.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications are 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 applications of this type.

EFFICACY

These applications are identical to the previously granted application for Boots Paracetamol Capsules 500mg (PL 00014/0442, The Boots Company plc).

No new or unexpected safety concerns arise from these applications.

PRODUCT LITERATURE

The approved SmPCs, PILs and labelling are satisfactory and consistent with those of the cross-reference product.

Package leaflets have been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflets are well-structured and organised, easy to understand and written in a comprehensive manner. The testing shows that patients/users are able to act upon the information that the leaflets contain.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. The name of the product in Braille appears on the outer packaging.

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. The risk: benefit is considered to be positive.

PARACETAMOL 500MG CAPSULES

(paracetamol)

PL 31308/0004-6

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the marketing authorisation applications on 28th March 2008
- 2 Following standard checks and communication with the applicant the MHRA considered the applications valid on 15th April 2008
- 3 Following assessment of the applications the MHRA requested further information relating to the quality dossier on 23rd September 2008 and 9th October 2009
- 4 The applicant responded to the MHRA's requests, providing further information for the quality sections on 27th May 2009 and 17th November 2009 respectively
- 5 The applications were determined on 16th December 2009

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Paracetamol 500mg Capsules is as follows. Differences between the individual SmPCs are highlighted.

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 500mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 500 mg paracetamol.

3 PHARMACEUTICAL FORM

Capsules, hard

White and blue hard capsules with no markings.

For a full list of excipients, see section 6.1.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of headaches, migraine, rheumatic, muscular and back pain, neuralgia, toothache and period pain and to relieve the symptoms of colds and flu.

4.2 Posology and method of administration

For oral use.

Unless, otherwise directed by the doctor:

Adults and children over 12 years of age

One to two capsules. The dose can be taken three to four times in any 24 hour period, at least four hours apart. Do not take more than eight capsules in 24 hours.

Do not take these capsules for more than three days without consulting your doctor.

Children under 12 years of age

Not recommended.

Elderly

There is no need for dosage reduction in the elderly.

4.3 Contraindications

Hypersensitivity to paracetamol and/or any of the other ingredients. Severe liver disease.

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 exceed the stated dose.

Not to be given to children under 12 years.

Dosage should not be continued for more than three days without consulting your doctor.

If symptoms persist, consult your doctor.

Do not take with any other paracetamol-containing products.

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

Label: Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Leaflet or combined label/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.

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 cholestyramine.

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.

4.6 Pregnancy and lactation

Pregnancy

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.

Lactation

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

4.7 Effects on ability to drive and use machines

Paracetamol 500mg Capsules has no known influence on the ability to drive and use machines.

4.8 Undesirable effects

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

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, 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 24 h from ingestion should be discussed with the NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Analgesics and Antipyretics - Anilides

ATC Code - N02BE01

Paracetamol is a peripherally acting analgesic with antipyretic activity.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependent.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents

Magnesium stearate
Sodium starch glycollate
Sodium lauryl sulphate

Capsule shell

Indigo carmine E132
Titanium dioxide E171
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package.

6.5 Nature and contents of container

For PL 31308/0004:

Child-resistant blisters of 250µm PVC/ 40gsm PVdC/ 35gsm Glassine Paper/ 9µm Soft Temper Aluminium foil. Pack sizes of 6, 8, 10, 12, 16 capsules (not all pack sizes will be marketed).

For PL 31308/0005:

Child-resistant blisters of 250µm PVC/ 40gsm PVdC/ 35gsm Glassine Paper/ 9µm Soft Temper Aluminium foil. Pack sizes of 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, 32 capsules (not all pack sizes will be marketed).

For PL 31308/0006:

Child-resistant blisters of 250µm PVC/ 40gsm PVdC/ 35gsm Glassine Paper/ 9µm Soft Temper Aluminium foil. Pack sizes of 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, 32, 36, 48, 96 capsules (not all pack sizes will be marketed).

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Max Remedies Ltd
Stoney Gate House
2 Greenfield Road
Holmfirth
West Yorkshire
HD9 2JT

8 MARKETING AUTHORISATION NUMBER(S)

PL 31308/0004
PL 31308/0005
PL 31308/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/12/2009

10 DATE OF REVISION OF THE TEXT

16/12/2009

PATIENT INFORMATION LEAFLET

PL 31308/0004



Information for the user

Paracetamol 500mg Capsules

Read this leaflet carefully because it contains important information for you.

This medicine is available without prescription for you to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a pharmacist or doctor if your symptoms worsen or do not improve after 3 days.

What this medicine is for

This medicine contains paracetamol, which belongs to a group of medicines called analgesics and antipyretics to relieve pain and reduce fever.

It can be used to relieve headache, migraine, rheumatic or muscular pain, backache, neuralgia, toothache, period pain and the symptoms of colds and flu.

Before you take this medicine

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take

- If you are allergic to any of the ingredients
- If you have severe liver disease

Talk to your pharmacist or doctor

- If you have kidney problems
- If you have other liver problems (including a disease caused by drinking alcohol)
- If you are pregnant

You can take this medicine if you are breastfeeding.

If you take other medicines

This medicine contains paracetamol.

Do not take with any other paracetamol-containing products.

Before you take these capsules, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Domperidone or metoclopramide, for feeling sick or being sick (may increase the pain relief effect of paracetamol)
- Colestyramine, for lowering blood lipid levels (may reduce the pain relief effect of paracetamol)
- Warfarin or other coumarins (for thinning the blood) – if you take warfarin you can take occasional doses of this medicine, but talk to your doctor first before you take it on a regular basis

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicines you have bought yourself, including herbal and homeopathic remedies.

How to take this medicine

Check the foil is not broken before use. If it is, do not take that capsule.

Follow the instructions in the table below.

Age	How many to take	How often to take
Adults and children of 12 years and over	One to two	Three or four times a day if you need to
<p>Do not take more than 8 capsules in 24 hours. Do not take more often than every 4 hours.</p>		

Swallow each capsule with water.

Do not give to children under 12 years.

Do not take more than the amount recommended above.

If symptoms do not go away within 3 days talk to your doctor.

If symptoms persist talk to your doctor.

If you take too many capsules:

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.

Possible side effects

Most people will not have problems, but some may get some.

If you get any of these serious side effects, stop taking the capsules. See a doctor at once:

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

These other effects are less serious, if they bother you talk to a pharmacist:

- Other allergic reactions (e.g. skin rash)
- Unusual bruising, or infections such as sore throats – this may be a sign of very rare changes in the blood

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

How to store this medicine

Do not store above 30°C. Store in the original package.

Keep all medicines out of the sight and reach of children, preferably in a locked cupboard.

Do not use after the Use By date on the end flap of the carton (marked 'EXP').

What is in this medicine

Each capsule contains Paracetamol 500mg, which is the active ingredient.

As well as the active ingredient, the capsules also contain sodium starch glycollate, magnesium stearate, sodium lauryl sulphate. The capsule shell contains gelatin, indigo carmine (E132), titanium dioxide (E171).

The pack contains 6, 8, 10, 12 or 16 capsules with a blue cap and white body (not all pack sizes may be marketed).

Who makes this medicine

The medicine is manufactured for the Marketing Authorisation holder Max Remedies Ltd, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire HD9 2JT by Hamol Limited, Nottingham NG90 2DB.

Leaflet prepared October 2009.

If you would like any further information about this product, please contact Max Healthcare Ltd, Waterside, Digley Road, Holmbridge HD9 2QN.

PL 31308/0005



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This medicine is available without prescription for you to treat minor conditions. However, you still need to take it carefully to get the best results from it.

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- Ask your pharmacist if you need more information or advice.
- You must contact a pharmacist or doctor if your symptoms worsen or do not improve after 3 days.

What this medicine is for

This medicine contains paracetamol, which belongs to a group of medicines called analgesics and antipyretics to relieve pain and reduce fever.

It can be used to relieve headache, migraine, rheumatic or muscular pain, backache, neuralgia, toothache, period pain and the symptoms of colds and flu.

Before you take this medicine

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take

- If you are allergic to any of the ingredients
- If you have severe liver disease

Talk to your pharmacist or doctor

- If you have kidney problems
- If you have other liver problems (including a disease caused by drinking alcohol)
- If you are pregnant

You can take this medicine if you are breastfeeding.

If you take other medicines

This medicine contains paracetamol.

Do not take with any other paracetamol-containing products.

Before you take these capsules, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Domperidone or metoclopramide, for feeling sick or being sick (may increase the pain relief effect of paracetamol)
- Colestyramine, for lowering blood lipid levels (may reduce the pain relief effect of paracetamol)
- Warfarin or other coumarins (for thinning the blood) – if you take warfarin you can take occasional doses of this medicine, but talk to your doctor first before you take it on a regular basis

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicines you have bought yourself, including herbal and homeopathic remedies.

How to take this medicine

Check the foil is not broken before use. If it is, do not take that capsule.

Follow the instructions in the table below.

Age	How many to take	How often to take
Adults and children of 12 years and over	One to two	Three or four times a day if you need to
Do not take more than 8 capsules in 24 hours. Do not take more often than every 4 hours.		

Swallow each capsule with water.

Do not give to children under 12 years.

Do not take more than the amount recommended above.

If symptoms do not go away within 3 days talk to your doctor.

If symptoms persist talk to your doctor.

If you take too many capsules:

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.

Possible side effects

Most people will not have problems, but some may get some.

If you get any of these serious side effects, stop taking the capsules. See a doctor at once:

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

These other effects are less serious, if they bother you talk to a pharmacist:

- Other allergic reactions (e.g. skin rash)
- Unusual bruising, or infections such as sore throats – this may be a sign of very rare changes in the blood

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

How to store this medicine

Do not store above 30°C. Store in the original package.

Keep all medicines out of the sight and reach of children, preferably in a locked cupboard.

Do not use after the Use By date on the end flap of the carton (marked 'EXP').

What is in this medicine

Each capsule contains Paracetamol 500mg, which is the active ingredient.

As well as the active ingredient, the capsules also contain sodium starch glycollate, magnesium stearate, sodium lauryl sulphate. The capsule shell contains gelatin, indigo carmine (E132), titanium dioxide (E171).

The pack contains 6, 8, 10, 12, 16, 18, 20, 24, 25, 30 or 32 capsules with a blue cap and white body (not all pack sizes may be marketed).

Who makes this medicine

The medicine is manufactured for the Marketing Authorisation holder Max Remedies Ltd, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire HD9 2JT by Hamol Limited, Nottingham NG90 2DB.

Leaflet prepared October 2009.

If you would like any further information about this product, please contact Max Healthcare Ltd, Waterside, Digley Road, Holmbridge HD9 2QN.

PL 31308/0006



Information for the user

Paracetamol 500mg Capsules

Read this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must contact a pharmacist or doctor if your symptoms worsen or do not improve after 3 days.

What this medicine is for

This medicine contains paracetamol, which belongs to a group of medicines called analgesics and antipyretics to relieve pain and reduce fever.

It can be used to relieve headache, migraine, rheumatic or muscular pain, backache, neuralgia, toothache, period pain and the symptoms of colds and flu.

Before you take this medicine

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take

- If you are allergic to any of the ingredients
- If you have severe liver disease

Talk to your pharmacist or doctor

- If you have kidney problems
- If you have other liver problems (including a disease caused by drinking alcohol)
- If you are pregnant

You can take this medicine if you are breastfeeding.

If you take other medicines

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Before you take these capsules, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Domperidone or metoclopramide, for feeling sick or being sick (may increase the pain relief effect of paracetamol)
- Colestyramine, for lowering blood lipid levels (may reduce the pain relief effect of paracetamol)
- Warfarin or other coumarins (for thinning the blood) – if you take warfarin you can take occasional doses of this medicine, but talk to your doctor first before you take it on a regular basis

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicines you have bought yourself, including herbal and homeopathic remedies.

How to take this medicine

Check the foil is not broken before use. If it is, do not take that capsule.

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Age	How many to take	How often to take
Adults and children of 12 years and over	One to two	Three or four times a day if you need to
<p>Do not take more than 8 capsules in 24 hours. Do not take more often than every 4 hours.</p>		

Swallow each capsule with water.

Do not give to children under 12 years.

Do not take more than the amount recommended above.

If symptoms do not go away within 3 days talk to your doctor.

If symptoms persist talk to your doctor.

If you take too many capsules:

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.

Possible side effects

Most people will not have problems, but some may get some.

If you get any of these serious side effects, stop taking the capsules. See a doctor at once:

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

These other effects are less serious, if they bother you talk to a pharmacist:

- Other allergic reactions (e.g. skin rash)
- Unusual bruising, or infections such as sore throats – this may be a sign of very rare changes in the blood

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

How to store this medicine

Do not store above 30°C. Store in the original package.

Keep all medicines out of the sight and reach of children, preferably in a locked cupboard.

Do not use after the Use By date on the end flap of the carton (marked 'EXP').

What is in this medicine

Each capsule contains Paracetamol 500mg, which is the active ingredient.

As well as the active ingredient, the capsules also contain sodium starch glycollate, magnesium stearate, sodium lauryl sulphate. The capsule shell contains gelatin, indigo carmine (E132), titanium dioxide (E171).

The pack contains 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, 32, 36, 48 or 96 capsules with a blue cap and white body (not all pack sizes may be marketed).

Who makes this medicine

The medicine is manufactured for the Marketing Authorisation holder Max Remedies Ltd, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire HD9 2JT by Hamol Limited, Nottingham NG90 2DB.

Leaflet prepared October 2009.

If you would like any further information about this product, please contact Max Healthcare Ltd, Waterside, Digley Road, Holmbridge HD9 2QN.

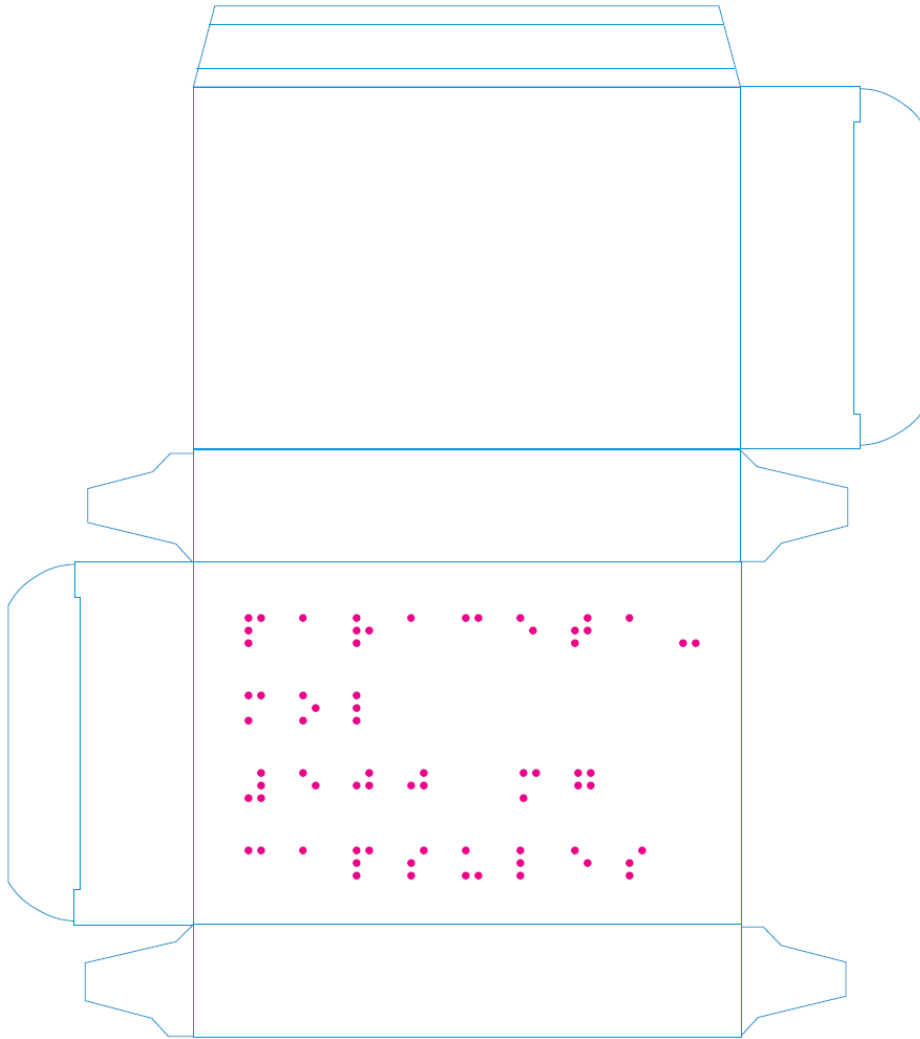
LABELLING

PL 31308/0004

Carton



Braille

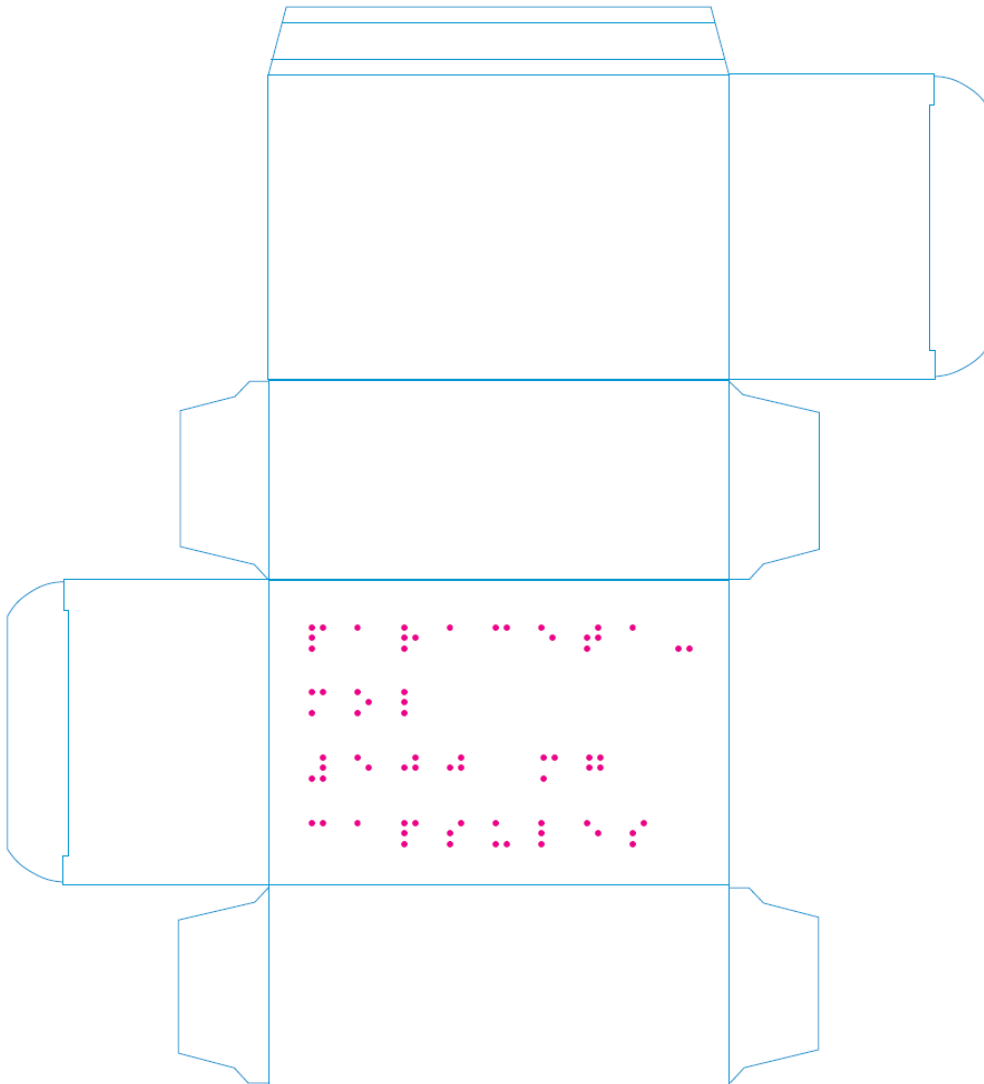


Blister foil



Lot and EXP to be embossed here at the time of packing

Braille



Blister foil



Lot and EXP to be embossed here at the time of packing

