PARACETAMOL 125MG, 250MG, 500MG AND 1000MG SUPPOSITORIES

PL 12762/0414-0417

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PARACETAMOL 125MG, 250MG, 500MG AND 1000MG SUPPOSITORYs

PL 12762/0414-0417

LAY SUMMARY

On 02 November 2011, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Goldshield pharmaceuticals Limited Marketing Authorisations (licences) for the medicinal products Paracetamol 125mg, 250mg, 500mg and 1000mg Suppositories (PL 12762/0414-0417). These are pharmacy (P) medicines.

Paracetamol 125mg is indicated for the relief of pain and to treat high temperature (fever) in children from 1 to 5 years of age.

Paracetamol 250mg Suppositories is indicated for the relief of pain and to treat high temperature (fever) in children from 6 to 12 years of age and adults.

Paracetamol 500mg Suppositories is indicated for the relief of pain and to treat high temperature (fever) in children over 10 years of age and adults.

Paracetamol 1000mg Suppositories is indicated for the relief of pain and to treat high temperature (fever) in adults.

Paracetamol 125mg, 250mg, 500mg and 1000mg Suppositories contain an active ingredient known as paracetamol. This belongs to a group of medicines called pain-killers (analgesics). A suppository is a small, torpedo-shaped, medicine which is inserted into the back passage (rectum). They are used in people who find it difficult to take paracetamol as tablets or syrup.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Paracetamol 125mg, 250mg, 500 and 1000mg Suppositories outweigh the risks; hence Marketing Authorisations were granted.
PARACETAMOL 125MG, 250MG, 500MG AND 1000MG SUPPOSITORY

PL 12762/0414-0417

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Goldshield pharmaceuticals Limited Marketing Authorisations for the medicinal products Paracetamol 125mg, 250mg, 500 and 1000mg Suppositories (PL 12762/0414-417) on 02 November 2011. These are pharmacy (P) medicines.

Paracetamol 125mg Suppositories is indicated for the treatment of mild to moderate pain and fever in children from 1 to 5 years of age.

Paracetamol 250mg, 500mg and 1000mg Suppositories are indicated for the treatment of mild to moderate pain such as toothache and/or pyrexia in children 6 years and over and adults.

Paracetamol 125mg, 250mg, 500 and 1000mg Suppositories may be especially useful in patients unable to take oral forms of paracetamol for example, post-operatively or with nausea and vomiting.

The applications were submitted as bibliographic applications, for an active of well-established use, according to Article 10(a) of Directive 2001/83/EC, as amended.

Paracetamol 125mg, 250mg, 500 and 1000mg Suppositories contain the active ingredient paracetamol which is an aniline derivative with analgesic and antipyretic actions similar to those of aspirin but with no demonstrable anti-inflammatory activity. Paracetamol does not affect thrombocyte aggregation or bleeding time. Paracetamol is generally well tolerated by patients hypersensitive to acetylsalicylic acid. It produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulation centre.

No new non-clinical studies were conducted for these applications, which is acceptable given that these are bibliographic applications for products containing an active of well-established use.

The Marketing Authorisation Holder has submitted three bioequivalence studies to support these applications. However, no new clinical studies are required for these applications, which is acceptable given that these are bibliographic applications for products containing an active of well-established use.

No new or unexpected safety concerns were raised during the assessment of these applications and it was, therefore, judged that the benefits of using Paracetamol 125mg, 250mg, 500 and 1000mg Suppositories outweigh the risks; hence Marketing Authorisations were granted.
PAR Paracetamol 125mg, 250mg, 500mg and 1000mg Suppositories PL 12762/0414-417

PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE:
INN: Paracetamol
Chemical Name: N-(4-hydroxyphenyl)acetamide
Structure:

\[
\begin{align*}
\text{H}_3C & \text{N} \\
\text{O} & \text{OH} \\
\end{align*}
\]

Molecular Formula: $\text{C}_8\text{H}_9\text{NO}_2$
Molecular weight: 151.2
Appearance: A white, crystalline powder.
Solubility: It is sparingly soluble in water, freely soluble in alcohol and very slightly soluble in dichloromethane.

Paracetamol is the subject of a European Pharmacopoeia monograph.

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

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

Appropriate stability data have been generated to support a suitable retest period for the active substance when stored in the proposed packaging.

MEDICINAL PRODUCT
Other Ingredients
Other ingredients consist of the pharmaceutical excipients, namely hydrogenated fat and soyabean lecithin.

Hydrogenated fat complies with its respective European Pharmacopoeia monograph and soyabean lecithin complies with its respective United States Pharmacopoeia monograph. Suitable batch analysis data have been provided for each excipient.

None of the excipients contain materials of animal or human origin. No genetically modified organisms (GMO) have been used in the preparation of these excipients.

Pharmaceutical Development
The objective of the development programme was to formulate safe, efficacious, stable products containing the active ingredient paracetamol.
Suitable pharmaceutical development data have been provided for these applications.

Comparative dissolution data were provided for batches of the test products and appropriate reference products. The dissolution profiles were satisfactory.

**Manufacturing Process**
A description and flow-chart of the manufacturing method have been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation data have been provided.

**Finished Product Specification**
The finished product specifications proposed are satisfactory. Test methods have been described and have been adequately validated. Batch data have been provided and comply with the release specifications.

**Container Closure System**
The finished products are packaged in polyvinyl chloride (PVC) blister packs and packaged into cartons in pack sizes of 10 suppositories.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging are controlled to current European Pharmacopoeia standards and complies with guidelines concerning materials in contact with food and guidelines concerning plastic packaging for pharmaceutical use.

**Stability of the Product**
Stability studies were performed in accordance with current guidelines on batches of finished products packed in the packaging proposed for marketing. These data support a shelf-life of 36 months for the finished products which is satisfactory. Storage conditions are ‘Do not store above 30°C’

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

**Bioequivalence/Bioavailability**
Bioequivalence studies were not necessary to support this type of applications. However, the Marketing Authorisation Holder has submitted three bioequivalence studies as supporting evidence but the data had no real impact on the assessment decision

**Summary of Product Characteristics (SmPC), Product Information Leaflets (PILs) and Labelling**
The SmPCs, PILs and labelling are pharmaceutically satisfactory.
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, as amended. The results indicate that the package leaflets are well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

**MAA Form**
The MAA forms are satisfactory.

**Expert Report**
The pharmaceutical expert report is written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

**Conclusion**
The grant of Marketing Authorisations is recommended.
NON-CLINICAL ASSESSMENT

PHARMACODYNAMICS, PHARMACOKINETICS AND TOXICOLOGY
No new non-clinical data were submitted, which is acceptable given that these were bibliographic applications for products containing active substance of well-established use.

NON-CLINICAL EXPERT REPORT
The non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the non-clinical aspects of the dossier.

CONCLUSION
The grant of Marketing Authorisations is recommended.
CLINICAL ASSESSMENT

CLINICAL PHARMACOLOGY
The clinical pharmacology of paracetamol is well-known. With the exception of data from the bioequivalence studies, no new pharmacodynamic or pharmacokinetic data are provided or required for these applications.

EFFICACY
No new efficacy data were submitted or required for these applications. The Clinical Efficacy of paracetamol in the alleviation of mild to moderate pain and fever can be considered well established. The clinical overview provides a comprehensive summary of the published data.

SAFETY
No new safety data were submitted or required for these applications. The applicant has provided an acceptable safety review from the literature. No new safety issues have been raised from these applications.

PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN
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 an adequate justification for not submitting a Risk Management Plan (RMP). As the applications concern are well established use and the active substances are well known, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC), PRODUCT FORMATION LEAFLETS (PILs) AND LABELS
The SmPCs, PILs and labels are acceptable.

CLINICAL EXPERT REPORT
The clinical expert report has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

CONCLUSION
The grant of Marketing Authorisations is recommended.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
The important quality characteristics of Paracetamol 125mg, 250mg, 500 and 1000mg Suppositories are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit-risk balance.

NON-CLINICAL
No new non-clinical data were submitted and none were required for this type of applications. A non-clinical overview has been provided by an appropriately qualified person and consists of a review of the published literature.

EFFICACY
No new data were submitted and none were required for this type of applications.

The published literature supports the efficacy of this product in the proposed indication. The efficacy of paracetamol in general is clearly demonstrated by the applicant via an extensive literature search, spanning a long period of time. The efficacy of paracetamol is well-known. The presented evidence for well-established use of the active substance is sufficient.

SAFETY
The safety profiles of paracetamol are well-known. The literature review identified no new or unexpected safety issues or concerns.

PRODUCT LITERATURE
The approved SmPCs are satisfactory. The PILs and labelling are satisfactory, and consistent with the approved SmPCs.

BENEFIT-RISK ASSESSMENT
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Paracetamol is a well-known active substance. Extensive clinical experience with paracetamol demonstrated the therapeutic value of the products. The benefit-risk is, therefore, considered to be positive.
PARACETAMOL 125MG, 250MG, 500MG AND 1000MG SUPPOSITORIES

PL 12762/0414-0417

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the marketing authorisation applications on 11 June 2009.

2 Following standard checks and communication with the applicant the MHRA considered the applications valid on 17 June 2009.

3 Following assessment of the applications the MHRA requested further information relating to the clinical dossier on 18 August 2009 and 07 October 2009, 26 October 2010 and 06 July 2011, and the quality dossier on 16 September 2009 and 22 June 2010.

4 The applicant responded to the MHRA’s requests, providing further information on the clinical dossier on 02 October 2009 and 08 January 2010, 26 November 2010 and 21 September 2011 and on the quality dossier on 11 August 2010.

5 The applications were determined and granted on 02 November 2011.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Paracetamol 125mg Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each suppository contains Paracetamol 125mg
For excipients, see 6.1

3 PHARMACEUTICAL FORM
Suppositories

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the treatment of mild to moderate pain and fever. Paracetamol Suppositories may be especially useful in patients unable to take oral forms of paracetamol, e.g. post-operatively or with nausea and vomiting.

4.2 Posology and method of administration
Method of administration: Rectal
Children:
1 year – 5 years: 1-2 suppositories every 4 to 6 hours
Dosages should be based on the child’s age and weight i.e.
1 year (10kg) – 125mg (1 suppository)
5 years (20kg) – 250mg (2 suppositories)
These doses may be repeated up to a maximum of 4 times in 24 hours. The dose should not be repeated more frequently than every 4 hours. The recommended dose should not be exceeded. Higher doses do not produce any increase in analgesic effect. The product should not be used for more than 3 days, except on the advice of a doctor. Only whole suppositories should be administered – do not break the suppository before administration

4.3 Contraindications
Hypersensitivity to either paracetamol, soy, peanuts or any of the other ingredients.

4.4 Special warnings and precautions for use
Paracetamol Suppositories should not be combined with other analgesic medications that contain paracetamol. Paracetamol should be given with care to patients with impaired kidney or liver function.
In general, the habitual use of painkillers, especially with combinations of more than one pain killing active ingredient, can lead to permanent kidney damage with the risk of liver failure (analgesic nephropathy).

Label and Leaflet will state the following warnings:

Label:
“Immediate medical advice should be sought in the event of an overdose, even if the child seems well”.
“Do not give with any other Paracetamol-containing products.”

Leaflet:
“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.”

4.5 Interaction with other medicinal products and other forms of interaction
The absorption of paracetamol is speeded by metaclopramide or domperidone, and absorption is reduced by colestyramine.
The anticoagulant effect of warfarin and other coumarins may be increased by long term regular daily use of paracetamol, with increased risk of bleeding. Occasional doses of paracetamol do not have a significant effect on these anticoagulants.
Enzyme-inducing medicines, such as some antiepileptic drugs (phenytoin, phenobarbital, carbamazepine) have been shown in pharmacokinetic studies to reduce the plasma AUC of paracetamol to approx. 60%. Other substances with enzyme-inducing properties, e.g. rifampicin are also suspected of causing lowered concentrations of paracetamol. In addition, the risk of liver damage during treatment with maximum recommended doses of paracetamol will be higher in patients being treated with enzyme-inducing agents.

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 amounts. Available published data do not contraindicate breast feeding.

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

4.8 Undesirable effects

<table>
<thead>
<tr>
<th>Common</th>
<th>Miscellaneous:</th>
<th>Redness of the rectal mucous membranes</th>
</tr>
</thead>
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<td>&gt;1/100</td>
<td>General:</td>
<td>Allergic reactions including skin rashes</td>
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<tr>
<td>&lt;1/1000</td>
<td>Skin:</td>
<td>Exanthema, urticaria</td>
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</tr>
<tr>
<td></td>
<td>Genitourinary:</td>
<td>Increase in creatinine (mostly secondary to hepatorenal syndrome)</td>
</tr>
</tbody>
</table>

There have been some reports of blood dyscrasias including thrombocytopenia and agranulocytosis, with the use of paracetamol-containing products, but the causal relationship has not been established.

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). It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue.

**Risk Factors:**
- If the patient
  1. Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.
  - Or
  2. Regularly consumes ethanol in excess of recommended amounts
  - Or
  3. 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 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 by mouth 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 NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic Group: Anilides, ATC Code: N02 BE01
Paracetamol is an aniline derivative with analgesic and antipyretic actions similar to those of aspirin but with no demonstrable anti-inflammatory activity. It does not affect thrombocyte aggregation or bleeding time. Paracetamol is generally well tolerated by patients hypersensitive to acetylsalicylic acid. It produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulation centre.

5.2 Pharmacokinetic properties
Paracetamol is well absorbed by both oral and rectal routes. Peak plasma concentrations occur about 2 to 3 hours after rectal administration. The plasma half life is about 2 ¼ hours and is prolonged in cirrhosis.
Paracetamol is primarily metabolised in the liver by conjugation to glucuronide and sulphate. A small amount (about 3-10% of a therapeutic dose) is metabolised by oxidation and the reactive intermediate metabolite thus formed is bound preferentially to the liver glutathione and excreted as cysteine and mercapturic acid conjugates. Excretion occurs via the kidneys. 2-3% of a therapeutic dose is excreted unchanged; 80-90% as glucuronide and sulphate and a smaller amount as cysteine and mercapturic acid derivatives.

5.3 Preclinical safety data
Paracetamol crosses the placenta.
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Hydrogenated fat
Soyabean Lecithin

6.2 Incompatibilities
None relevant

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container
PVC-Blister packet
In pack size of 10 suppositories

6.6 Special precautions for disposal
None

7 MARKETING AUTHORISATION HOLDER
Goldshield Pharmaceuticals Ltd
NLA Tower 12-16 Addiscombe Road
Croydon CR0 0XT
United Kingdom

8 MARKETING AUTHORIZATION NUMBER(S)
PL 12762/0414

9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
02/11/2011

10 DATE OF REVISION OF THE TEXT
02/11/2011

11 DOSIMETRY (IF APPLICABLE)
Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS
( IF APPLICABLE)
Not Applicable
1 **NAME OF THE MEDICINAL PRODUCT**
Paracetamol 250mg Suppositories

2 **QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each suppository contains Paracetamol 250mg
For excipients, see 6.1

3 **PHARMACEUTICAL FORM**
Suppositories

4 **CLINICAL PARTICULARS**

4.1 **Therapeutic indications**
For the treatment of mild to moderate pain such as toothache and/or pyrexia. Paracetamol Suppositories may be especially useful in patients unable to take oral forms of paracetamol, e.g. post-operatively or with nausea and vomiting.

4.2 **Posology and method of administration**
Method of administration: Rectal
Children:
6 – 9 years (20 – 30kg): 1 suppository every 4 to 6 hours
10 – 12 years (30 – 40kg): 1-2 suppositories every 4 to 6 hours
Dosages should be based on the child’s age and weight. These doses may be repeated up to a maximum of 4 times in 24 hours. The dose should not be repeated more frequently than every 4 hours. The recommended dose should not be exceeded. Higher doses do not produce any increase in analgesic effect. The product should not be used for more than 3 days, except on the advice of a doctor. Only whole suppositories should be administered – do not break the suppository before administration.

4.3 **Contraindications**
Hypersensitivity to either paracetamol, soy, peanuts or any of the other ingredients.

4.4 **Special warnings and precautions for use**
Paracetamol Suppositories should not be combined with other analgesic medications that contain paracetamol. Paracetamol should be given with care to patients with impaired kidney or liver function.
In general, the habitual use of painkillers, especially with combinations of more than one pain killing active ingredient, can lead to permanent kidney damage with the risk of liver failure (*analgetic nephropathy*).

Label and Leaflet will state the following warnings:
Label:
“Immediate medical advice should be sought in the event of an overdose, even if the child seems well”.
“Do not give with any other Paracetamol-containing products.”
Leaflet:
“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.”

4.5 **Interaction with other medicinal products and other forms of interaction**
The absorption of paracetamol is speeded by metaclopramide or domperidone, and absorption is reduced by colestyramine.
The anticoagulant effect of warfarin and other coumarins may be increased by long term regular daily use of paracetamol, with increased risk of bleeding. Occasional doses of paracetamol do not have a significant effect on these anticoagulants.
Enzyme-inducing medicines, such as some antiepileptic drugs (phenytoin, phenobarbital, carbamazepine) have been shown in pharmacokinetic studies to reduce the plasma AUC of paracetamol to approx. 60%. Other substances with enzyme-inducing properties, e.g.
rifampicin are also suspected of causing lowered concentrations of paracetamol. In addition, the risk of liver damage during treatment with maximum recommended doses of paracetamol will be higher in patients being treated with enzyme-inducing agents.

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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.

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None known.

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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). It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue.

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 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 by mouth 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 NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic Group: Anilides, ATC Code: N02 BE01
Paracetamol is an aniline derivative with analgesic and antipyretic actions similar to those of aspirin but with no demonstrable anti-inflammatory activity. It does not affect thrombocyte aggregation or bleeding time. Paracetamol is generally well tolerated by patients hypersensitive to acetylsalicylic acid. It produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulation centre.

5.2 Pharmacokinetic properties
Paracetamol is well absorbed by both oral and rectal routes. Peak plasma concentrations occur about 2 to 3 hours after rectal administration. The plasma half life is about 2 ¼ hours and is prolonged in cirrhosis.

Paracetamol is primarily metabolised in the liver by conjugation to glucuronide and sulphate. A small amount (about 3-10% of a therapeutic dose) is metabolised by oxidation and the reactive intermediate metabolite thus formed is bound preferentially to the liver glutathione and excreted as cystein and mercapturic acid conjugates. Excretion occurs via the kidneys. 2-3% of a therapeutic dose is excreted unchanged; 80-90% as glucuronide and sulphate and a smaller amount as cysteine and mercapturic acid derivatives.

5.3 Preclinical safety data
Paracetamol crosses the placenta.
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Hydrogenated fat
Soyabean Lecithin

6.2 Incompatibilities
None relevant

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container
PVC-Blister packet
In pack size of 10 suppositories

6.6 Special precautions for disposal
None
MARKETING AUTHORISATION HOLDER
Goldshield Pharmaceuticals Ltd
NLA Tower 12-16 Addiscombe Road
Croydon CR0 0XT
United Kingdom

MARKETING AUTHORISATION NUMBER(S)
PL 12762/0415

DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
02/11/2011

DATE OF REVISION OF THE TEXT
02/11/2011

DOSIMETRY (IF APPLICABLE)
Not Applicable

INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable
1 NAME OF THE MEDICINAL PRODUCT
Paracetamol 500mg Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each suppository contains Paracetamol 500mg
For excipients, see 6.1

3 PHARMACEUTICAL FORM
Suppositories

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the treatment of mild to moderate pain and fever. Paracetamol Suppositories may be especially useful in patients unable to take oral forms of paracetamol, e.g. post-operatively or with nausea and vomiting.

4.2 Posology and method of administration
Method of administration: Rectal
Children 10 years – 12 years (30-40kg):
1 suppository every 4 to 6 hours up to a maximum of 4 suppositories in 24 hours.

Adults + Children 12 years and over:
1 -2 suppositories every 4 to 6 hours up to a maximum of 8 suppositories in 24 hours.

Dosages should be based on the child’s age and weight. The dose should not be repeated more frequently than every 4 hours. The recommended dose should not be exceeded. Higher doses do not produce any increase in analgesic effect. The product should not be used for more than 3 days, except on the advice of a doctor. Only whole suppositories should be administered – do not break the suppository before administration.

4.3 Contraindications
Hypersensitivity to either paracetamol, soy, peanuts or any of the other ingredients.

4.4 Special warnings and precautions for use
Paracetamol Suppositories should not be combined with other analgesic medications that contain paracetamol. Paracetamol should be given with care to patients with impaired kidney or liver function.

In general, the habitual use of painkillers, especially with combinations of more than one pain killing active ingredient, can lead to permanent kidney damage with the risk of liver failure (analgesic nephropathy).

Label and Leaflet will state the following warnings:

Label:
“Immediate medical advice should be sought in the event of an overdose, even if the child seems well”.
“Do not give with any other Paracetamol-containing products.”

Leaflet:
“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.”

4.5 Interaction with other medicinal products and other forms of interaction
The absorption of paracetamol is speeded by metaclopramide or domperidone, and absorption is reduced by colestyramine.
The anticoagulant effect of warfarin and other coumarins may be increased by long term regular daily use of paracetamol, with increased risk of bleeding. Occasional doses of paracetamol do not have a significant effect on these anticoagulants.
Enzyme-inducing medicines, such as some antiepileptic drugs (phenytoin, phenobarbital, carbamazepine) have been shown in pharmacokinetic studies to reduce the plasma AUC of paracetamol to approx. 60%. Other substances with enzyme-inducing properties, e.g. rifampicin are also suspected of causing lowered concentrations of paracetamol. In addition, the risk of liver damage during treatment with maximum recommended doses of paracetamol will be higher in patients being treated with enzyme-inducing agents.

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 amounts. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

<table>
<thead>
<tr>
<th>Common</th>
<th>Miscellaneous:</th>
<th>Redness of the rectal mucous membranes</th>
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<tbody>
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<td>&gt;1/100</td>
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<td></td>
<td>Genitourinary:</td>
<td>Increase in creatinine (mostly secondary to hepatorenal syndrome)</td>
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</table>

There have been some reports of blood dyscrasias, including thrombocytopenia and agranulocytosis, with the use of paracetamol-containing products, but the causal relationship has not been established.

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). It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue.

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 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 by mouth 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 NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic Group: Anilides, ATC Code: N02 BE01
Paracetamol is an aniline derivative with analgesic and antipyretic actions similar to those of aspirin but with no demonstrable anti-inflammatory activity. It does not affect thrombocyte aggregation or bleeding time. Paracetamol is generally well tolerated by patients hypersensitive to acetylsalicylic acid. It produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulation centre.

5.2 Pharmacokinetic properties
Paracetamol is well absorbed by both oral and rectal routes. Peak plasma concentrations occur about 2 to 3 hours after rectal administration. The plasma half life is about 2 ¼ hours and is prolonged in cirrhosis.
Paracetamol is primarily metabolised in the liver by conjugation to glucuronide and sulphate. A small amount (about 3-10% of a therapeutic dose) is metabolised by oxidation and the reactive intermediate metabolite thus formed is bound preferentially to the liver glutathione and excreted as cystein and mercapturic acid conjugates. Excretion occurs via the kidneys. 2-3% of a therapeutic dose is excreted unchanged; 80-90% as glucuronide and sulphate and a smaller amount as cysteine and mercapturic acid derivatives.

5.3 Preclinical safety data
Paracetamol crosses the placenta.
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Hydrogenated fat
Soyabean Lecithin

6.2 Incompatibilities
None relevant

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C
6.5 Nature and contents of container
PVC-Blister packet
In pack size of 10 suppositories

6.6 Special precautions for disposal
None

7 MARKETING AUTHORISATION HOLDER
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02/11/2011

11 DOSIMETRY (IF APPLICABLE)
Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable
1 NAME OF THE MEDICINAL PRODUCT
Paracetamol 1000mg Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each suppository contains Paracetamol 1000mg
For excipients, see 6.1

3 PHARMACEUTICAL FORM
Suppositories

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the treatment of mild to moderate pain such as toothache and/or pyrexia. Paracetamol
Suppositories may be especially useful in patients unable to take oral forms of paracetamol,
e.g. post-operatively or with nausea and vomiting.

4.2 Posology and method of administration
Method of administration: Rectal

   Adults
   1 suppository every 4 to 6 hours up to a maximum of 4 suppositories in 24 hours.
   The dose should not be repeated more frequently than every 4 hours. The recommended dose
   should not be exceeded. Higher doses do not produce any increase in analgesic effect. The
   product should not be used for more than 3 days, except on the advice of a doctor. Only whole
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or liver function.

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pain killing active ingredient, can lead to permanent kidney damage with the risk of liver
failure (analgesic nephropathy).

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   “Immediate medical advice should be sought in the event of an overdose, even if the child
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c. Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Hydrogenated fat
Soyabean Lecithin

6.2 Incompatibilities
None relevant

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container
PVC-Blister packet
In pack size of 10 suppositories

6.6 Special precautions for disposal
None
PAR Paracetamol 125mg, 250mg, 500mg and 1000mg Suppositories

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11 DOSIMETRY (IF APPLICABLE)
Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable
PARacetamol 125mg, 250mg, 500mg and 1000mg Suppositories  PL 12762/0414-417

PATIENT INFORMATION LEAFLET

Patient Information Leaflet
PARACETAMOL 125mg SUPPOSITORIES
Paracetamol

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

- This medicine is available without prescription. However, you still need to use Paracetamol 125mg Suppositories carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if symptoms worsen or do not improve after 3 days.
- If any of the listed side effects get serious, or if you notice any side effects which are not listed in this leaflet, please tell your doctor or pharmacist.
- Your product is called Paracetamol 125mg Suppositories but will be referred to as Paracetamol Suppositories throughout this leaflet.

In this leaflet:
1. What Paracetamol Suppositories are and what they are used for
2. Before you use Paracetamol Suppositories
3. How to use Paracetamol Suppositories
4. Possible side effects
5. How to store Paracetamol Suppositories
6. Further information

1. WHAT PARACETAMOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR
Paracetamol Suppositories contain a medicine called paracetamol. This belongs to a group of medicines called pain-killers (analgesics). A suppository is a small, torpedo-shaped, medicine which is inserted into the back passage (rectum).
Paracetamol Suppositories are used to treat pain and high temperature (fever) in children from 1 to 5 years of age. They can be used in children who find it difficult to take paracetamol as tablets or syrup.

2. BEFORE YOU USE PARACETAMOL SUPPOSITORIES
Do not give Paracetamol Suppositories to your child if:
- your child is allergic (hypersensitive) to paracetamol, soya, peanuts or any of the other ingredients of Paracetamol Suppositories (listed in Section 6 at the end of this leaflet).
Take special care with the use of Paracetamol Suppositories and talk to your pharmacist or doctor if:
- your child has problems with their liver or kidneys.

Taking other medicines
Please tell your child’s doctor or pharmacist if your child is taking, or has recently taken, any other medicines, including medicines obtained without a prescription and herbal medicines. This is because Paracetamol Suppositories can have an affect on the way some medicines work and some medicines can have an affect on how Paracetamol Suppositories work.
In particular, tell your child’s doctor or pharmacist if your child is taking any of the following:
- Other medicines containing paracetamol – do not give your child Paracetamol Suppositories at the same time.
- Medicines to treat nausea (feeling sick) and vomiting (being sick), such as metoclopramide or domperidone
- Colestyramine, used to reduce the level of cholesterol (fat) in the blood.
- Medicines called anticoagulants, such as warfarin, used for treating blood clots
- Medicines called anticonvulsants used for treating epilepsy or fits (e.g. phenytoin, carbamazepine)
- The antibiotic rifampicin.

3. HOW TO USE PARACETAMOL SUPPOSITORIES
This medicine is for rectal use only. If your child’s doctor or pharmacist has told you how to use this medicine, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or are not sure, ask the doctor or pharmacist.

How many Paracetamol Suppositories to give your child:

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of Suppositories</th>
<th>Minimum Length of time between doses</th>
<th>Maximum number of suppositories in 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year (10kg)</td>
<td>1</td>
<td>4 - 6 hours</td>
<td>4</td>
</tr>
<tr>
<td>Over 1 year to 5 years (20kg)</td>
<td>1 or 2</td>
<td>4 - 6 hours</td>
<td>4 - 8</td>
</tr>
</tbody>
</table>
Do not give your child more suppositories than stated above.
Consult your child’s doctor if symptoms get worse or do not improve within 3 days.

How to use the suppositories:
• Your child’s bowels need to be empty when you give them this medicine. If your child needs to go to the toilet, make sure that they do it before you give them the suppository.
• It may be easier to give your child the suppository if they are lying on their front or side on a bed.
• Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.
• Gently push the suppository into your child’s back passage with the pointed end first. To make it easier to give the suppository you may warm it slightly between your hands beforehand.
• Try to keep your child still for a minute or two and then wash your hands.
• If you need to give another suppository, then follow the above procedure again.

If you have given more Paracetamol Suppositories to your baby than you should:
• Immediate medical advice should be sought in the event of an overdose, even if your child seems well, because of the risk of delayed, serious liver damage.

If you have any further questions regarding the use of this medication, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Suppositories can cause side effects, although not everybody gets them.

Stop giving Paracetamol Suppositories to your child immediately and call your doctor if you notice your child has any signs of allergic reaction.

Signs of an allergic reaction include a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

The following side effects can happen with this medicine.

Common side effects (affects more than 1 in 100 people taking this medicine):
• Redness or soreness in and around the back passage.

Rare side effects (affects less than 1 in 1000 people taking this medicine):
• Blood problems. If these happen, your child may bruise or bleed more easily than usual, be more susceptible to get infections, or get a high temperature (fever) and ulcers in the mouth and throat.
• Liver problems, symptoms may include jaundice (yellowing of the skin or whites of the eyes).

If your child gets any of the side effects mentioned above, or gets any side effect not mentioned in this leaflet, talk to your child’s doctor or pharmacist.

5. HOW TO STORE PARACETAMOL SUPPOSITORIES

Keep out of reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip. The expiry date refers to the last day of that month.

Do not store over 30°C.

6. FURTHER INFORMATION

What Paracetamol Suppositories contains:
The active substance is paracetamol. Each suppository contains 125mg of paracetamol.
The other ingredients are: hydrogenated fat, soya bean lecithin.

What Paracetamol Suppositories look like and contents of the pack:
Cream coloured, torpedo shaped suppository, available in packs of 10 suppositories.

Marketing authorisation holder:
Goldshilf Pharmaceuticals Ltd.,
NLA Tower, 12-16 Addiscombe Road,
Croydon, Surrey. CR0 0XT, UK.

Manufacturer:
Dr. R. Pfleger Chemische Fabrik GmbH,
D-90045 Bamberg.

This package leaflet was last revised in August 2011.
Goldshield

Patient Information Leaflet
PARACETAMOL 250mg SUPPOSITORY
Paracetamol

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Paracetamol 250mg Suppositories carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if symptoms worsen or do not improve after 3 days.
- If any of the listed side effects get serious, or if you notice any side effects which are not listed in this leaflet, please tell your doctor or pharmacist.
- Your product is called Paracetamol 250mg Suppositories but will be referred to as Paracetamol Suppositories throughout this leaflet.

In this leaflet:
1. What Paracetamol Suppositories are and what they are used for
2. Before you use Paracetamol Suppositories
3. How to use Paracetamol Suppositories
4. Possible side effects
5. How to store Paracetamol Suppositories
6. Further information

1. WHAT PARACETAMOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR
Paracetamol Suppositories contain a medicine called paracetamol. This belongs to a group of medicines called pain-killers (analgesics). A suppository is a small, torpedo-shaped, medicine which is inserted into the back passage (rectum).
Paracetamol Suppositories are used to treat pain and high temperature (fever) in children from 6 to 12 years of age. They can be used in children who find it difficult to take paracetamol as tablets or syrup.

2. BEFORE YOU USE PARACETAMOL SUPPOSITORIES
Do not give Paracetamol Suppositories to your child if:
• your child is allergic (hypersensitive) to paracetamol, soya, peanuts or any of the other ingredients of Paracetamol Suppositories (listed in Section 6 at the end of this leaflet).
Take special care with the use of Paracetamol Suppositories and talk to your pharmacist or doctor if:
• your child has problems with their liver or kidneys.

Taking other medicines
Please tell your child's doctor or pharmacist if, your child is taking, or has recently taken, any other medicines, including medicines obtained without a prescription and herbal medicines. This is because Paracetamol Suppositories can have an effect on the way some medicines work and some medicines can have an effect on how Paracetamol Suppositories work.
In particular tell your child's doctor or pharmacist if your child is taking any of the following:
• Other medicines containing paracetamol - do not give your child Paracetamol Suppositories at the same time
  • Medicines to treat nausea (feeling sick) and vomiting (being sick), such as metoclopramide and domperidone
  • Colestegmine, used to reduce the level of cholesterol (fat) in the blood
  • Medicines called anticoagulants, such as warfarin, used for treating blood clots or "thinning the blood"
  • Medicines called antiepileptics used for treating epilepsy or fits (e.g. phenytoin, carbamazepine)
  • The antibiotic rifampicin.

3. HOW TO USE PARACETAMOL SUPPOSITORIES
The medicine should only be used in children. If your child's doctor or pharmacist has told you how to use this medicine, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or are not sure, ask the doctor or pharmacist.
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<td>1</td>
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Do not give your child more suppositories than stated above.
Consult your child’s doctor if symptoms get worse or do not improve within 3 days.

**How to use the suppositories:**
- Your child’s bowels need to be empty when you give them this medicine. If your child needs to go to the toilet, make sure that they do it before you give them the suppository.
- It may be easier to give your child the suppository if they are lying on their front or side on a bed.
- Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.
- Gently push the suppository into your child’s back passage with the pointed end first. To make it easier to give the suppository you may warm it slightly between your hands beforehand.
- Try to keep your child still for a minute or two and then wash your hands.
- If you need to give another suppository, then follow the above procedure again.

**If you have given more Paracetamol Suppositories to your child than you should:**
- Immediate medical advice should be sought in the event of an overdose, even if your child seems well, because of the risk of delayed, serious liver damage.

If you have any further questions regarding the use of this medication, please ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Suppositories can cause side effects, although not everybody gets them.

Stop giving Paracetamol Suppositories to your child immediately and call your doctor if you notice your child has any signs of an allergic reaction.

Signs of an allergic reaction include a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

The following side effects can happen with this medicine:

**Common side effects (affects more than 1 in 100 people taking this medicine):**
- Redness or soreness in and around the back passage.

**Rare side effects (affects less than 1 in 1000 people taking this medicine):**
- Blood problems. If these happen, your child may bruise or bleed more easily than usual, be more susceptible to infections, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems. Symptoms may include jaundice (yellowing of the skin or whites of the eye).

If your child gets any of the side effects mentioned above, or gets any side effect not mentioned in this leaflet, talk to your child’s doctor or pharmacist.

### 5. HOW TO STORE PARACETAMOL SUPPOSITORIES

Keep out of reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip. The expiry date refers to the last day of that month.

Do not store over 30°C.

### 6. FURTHER INFORMATION

**What Paracetamol Suppositories contains:**
- The active substance is paracetamol. Each suppository contains 250mg of paracetamol.
- The other ingredients are: hydrogenated fat, soybean lecithin.

**What Paracetamol Suppositories look like and contents of the pack:**
- Cream coloured, torpedo shaped suppository, available in packs of 10 suppositories.

**Marketing authorisation holder:**
- Goldshield Pharmaceuticals Ltd., NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT, UK.

**Manufacturer:**
- Dr. R. Pfleger Chemische Fabrik GmbH, D-06045 Bamburg.

This package leaflet was last revised in August 2011.

10987/LF/1
Patient Information Leaflet

PARACETAMOL 500mg SUPPOSITORY

Paracetamol

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

This medicine is available without prescription. However, you still need to use Paracetamol 500mg Suppositories carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if symptoms worsen or do not improve after 3 days.
- If any of the listed side effects get serious, or if you notice any side effects which are not listed in this leaflet, please tell your doctor or pharmacist.
- Your product is called Paracetamol 500mg Suppositories but will be referred to as Paracetamol Suppositories throughout this leaflet.

In this leaflet:
1. What Paracetamol Suppositories are and what they are used for
2. Before you use Paracetamol Suppositories
3. How to use Paracetamol Suppositories
4. Possible side effects
5. How to store Paracetamol Suppositories
6. Further information

1. WHAT PARACETAMOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

Paracetamol Suppositories contain a medicine called paracetamol. This belongs to a group of medicines called painkillers (analgesics). A suppository is a small, torpedo-shaped, medicine which is inserted into the back passage (rectum).

Paracetamol Suppositories are used to treat pain and high temperature (fever) in adults and children over 10 years of age. They are used when it is difficult to take paracetamol as tablets or syrup.

2. BEFORE YOU USE PARACETAMOL SUPPOSITORIES

Do not use Paracetamol Suppositories if:
- you are allergic (hypersensitive) to paracetamol, soya, peanuts or any of the other ingredients of Paracetamol Suppositories (listed in Section 6 at the end of this leaflet);
- you have problems with your liver or kidneys.

Take special care with the use of Paracetamol Suppositories and talk to your pharmacist or doctor if:
- you have problems with your liver or kidneys.

Taking other medicines

Please tell your doctor or pharmacist if you take or have recently taken any other medicines including medicines obtained without a prescription and herbal medicines. This is because Paracetamol Suppositories can have an effect on the way some medicines work and some medicines can have an effect on how Paracetamol Suppositories work. In particular tell your doctor or pharmacist if you are taking any of the following:
- Other medicines containing paracetamol - do not use your Paracetamol Suppositories at the same time
- Medicines to treat nausea (feeling sick) and vomiting (being sick) such as metoclopramide and domperidone
- Colchicine, used to reduce the level of cholesterol (fat) in the blood
- Medicines called anticoagulants, such as warfarin, used for treating blood clots or “thinning the blood”
- Medicines called anticonvulsants used for treating epilepsy or fits (e.g. phenytoin, carbamazepine)
- The antibiotic rifampicin.

3. HOW TO USE PARACETAMOL SUPPOSITORIES

This medicine is for rectal use only. If your doctor or pharmacist has told you how to use this medicine, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or are not sure, ask the doctor or pharmacist.

How many Paracetamol Suppositories to use:

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of Suppositories</th>
<th>Minimum Length of time between doses</th>
<th>Maximum number of suppositories in 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 years to 12 years</td>
<td>1</td>
<td>4 - 6 hours</td>
<td>4</td>
</tr>
<tr>
<td>(body weight 30-40kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults over 12 years</td>
<td>1 or 2</td>
<td>4 - 6 hours</td>
<td>8</td>
</tr>
</tbody>
</table>

32
Paracetamol 125mg, 250mg, 500mg and 1000mg Suppositories

Do not use more suppositories than stated above.

This product is not suitable for use in children under 10 years of age.

Consult your doctor if your symptoms get worse or do not improve within 3 days.

How to use the suppositories:
- Your bowels need to be empty when you use this medicine. If you need to go to the toilet, make sure that you do it before you use the suppository.
- It may be easier to use the suppository if you are lying on your front or side on a bed.
- Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.
- Gently push the suppository into your back passage with the pointed end first. To make it easier to use the suppository you may warm it slightly between your hands beforehand.
- Try to keep still for a minute or two and then wash your hands.
- If you need to use another suppository, then follow the above procedure again.

If you have used more Paracetamol Suppositories than you should:
- Immediate medical advice should be sought in the event of an overdose, even if you seem well, because of the risk of delayed, serious liver damage.

If you have any further questions regarding the use of this medication, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Suppositories can cause side effects, although not everybody gets them.

Stop using Paracetamol Suppositories immediately and call your doctor if you notice you have any signs of allergic reaction.

Signs of an allergic reaction include a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

The following side effects can happen with this medicine:

Common side effects (affects more than 1 in 100 people taking this medicine):
- Redness or soreness in and around the back passage.

Rare side effects (affects less than 1 in 1000 people taking this medicine):
- Blood problems. If these happen, you may bruise or bleed more easily than usual, be more susceptible to infections, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems. Symptoms may include jaundice (yellowing of the skin or whites of the eyes).

If you get any of the side effects mentioned above, or get any side effect not mentioned in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE PARACETAMOL SUPPOSITORIES

Keep out of reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip. The expiry date refers to the last day of that month.

Do not store over 30°C.

6. FURTHER INFORMATION

What Paracetamol Suppositories contains:
The active substance is paracetamol. Each suppository contains 500mg of paracetamol.
The other ingredients are: hydrogenated fat, soyabean lecithin.

What Paracetamol Suppositories look like and contents of the pack:
Cream coloured, torpedo shaped suppository, available in packs of 10 suppositories.

Marketing authorisation holder:
Goldshield Pharmaceuticals Ltd.,
NLA Tower, 12-16 Addiscombe Road,
Croydon, Surrey CR0 0XT, UK.

Manufacturer:
Dr. R. Pflieger Chemische Fabrik GmbH,
D-99045 Bamberg.

This package leaflet was last revised in October 2011.

10989 LF/1
Patient Information Leaflet
PARACETAMOL 1000mg SUPPOSITORIES

Paracetamol

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Paracetamol 1000mg Suppositories carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if symptoms worsen or do not improve after 3 days.
- If any of the listed side effects get serious, or if you notice any side effects which are not listed in this leaflet, please tell your doctor or pharmacist.
- Your product is called Paracetamol 1000mg Suppositories but will be referred to as Paracetamol Suppositories throughout this leaflet.

In this leaflet:
1. What Paracetamol Suppositories are and what they are used for
2. Before you use Paracetamol Suppositories
3. How to use Paracetamol Suppositories
4. Possible side effects
5. How to store Paracetamol Suppositories
6. Further information

1. WHAT PARACETAMOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

Paracetamol Suppositories contain a medicine called paracetamol. This belongs to a group of medicines called painkillers (analgesics). A suppository is a small, torpedo-shaped medicine which is inserted into the back passage (rectum).
Paracetamol Suppositories are used to treat pain and high temperature (fever) in adults. They are used when it is difficult to take paracetamol as tablets or syrup.

2. BEFORE YOU USE PARACETAMOL SUPPOSITORIES

Do not use Paracetamol Suppositories if:
• you are allergic (hypersensitive) to paracetamol, soya, peanuts or any of the other ingredients of Paracetamol Suppositories (listed in Section 6 at the end of this leaflet).

Take special care with the use of Paracetamol Suppositories and talk to your pharmacist or doctor if:
• you have problems with your liver or kidneys.

Taking other medicines
Please tell your doctor or pharmacist if you take or have recently taken any other medicines including medicines obtained without a prescription and herbal medicines. This is because Paracetamol Suppositories can have an effect on the way some medicines work and some medicines can have an effect on how Paracetamol Suppositories work.
In particular tell your doctor or pharmacist if you are taking any of the following:
• Other medicines containing paracetamol – do not use your Paracetamol Suppositories at the same time
• Medicines to treat nausea (feeling sick) and vomiting (being sick), such as metoclopramide and domperidone
• Colestyramine, used to reduce the level of cholesterol (fat) in the blood
• Medicines called anticoagulants, such as warfarin, used for treating blood clots or thinning the blood
• Medicines called anti-convulsants used for treating epilepsy or fits (e.g. phenytoin, carbamazepine)
• The antibiotic rifampicin.

3. HOW TO USE PARACETAMOL SUPPOSITORIES

This medicine is for rectal use only. If your doctor or pharmacist has told you how to use this medicine, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or are not sure, ask the doctor or pharmacist.

How many Paracetamol Suppositories to use:

<table>
<thead>
<tr>
<th>Number of Suppositories</th>
<th>Minimum Length of time between doses</th>
<th>Maximum number of suppositories in 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4 - 6 hours</td>
<td>4</td>
</tr>
</tbody>
</table>

Do not use more suppositories than stated above.
This product is not suitable for use in children.
Consult your doctor if your symptoms get worse or do not improve within 3 days.
PAR Paracetamol 125mg, 250mg, 500mg and 1000mg Suppositories

How to use the suppositories:
- Your bowels need to be empty when you use this medicine. If you need to go to the toilet, make sure that you do it before you use the suppository.
- It may be easier to use the suppository if you are lying on your front or side on a bed.
- Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.
- Gently push the suppository into your back passage with the pointed end first. To make it easier to use the suppository you may warm it slightly between your hands beforehand.
- Try to keep still for a minute or two and then wash your hands.

If you have used more Paracetamol Suppositories than you should:
- Immediate medical advice should be sought in the event of an overdose, even if you seem well, because of the risk of delayed, serious liver damage.

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

Stop using Paracetamol Suppositories immediately and call your doctor if you notice you have any signs of allergic reaction.

Signs of an allergic reaction include a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

The following side effects can happen with this medicine.

Common side effects (affects more than 1 in 100 people taking this medicine):
- Redness or soreness in and around the back passage.

Rare side effects (affects less than 1 in 1000 people taking this medicine):
- Blood problems. If these happen, you may bruise or bleed more easily than usual, be more susceptible to infections, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems. Symptoms may include jaundice (yellowing of the skin or whites of the eyes).

If you get any of the side effects mentioned above, or get any side effect not mentioned in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE PARACETAMOL SUPPOSITORIES
Keep out of reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip. The expiry date refers to the last day of that month.

Do not store over 30°C.

6. FURTHER INFORMATION
What Paracetamol Suppositories contain:
The active substance is paracetamol. Each suppository contains 1000mg of paracetamol.
The other ingredients are: hydrogenated fat, soya lecithin.

What Paracetamol Suppositories look like and contents of the pack:
Cream coloured, torpedo shaped suppository, available in packs of 10 suppositories.

Marketing authorisation holder:
Goldfeld Pharmaceuticals Ltd.,
NLA Tower, 12-16 Addiscombe Road,
Croydon, Surrey CR0 0XT, UK.

Manufacturer:
Dr. Pfleger Chemische Fabrik GmbH,
D-96045 Bamberg.

This package leaflet was last revised in August 2011.
PAR Paracetamol 125mg, 250mg, 500mg and 1000mg Suppositories

BLISTER

BN/Use By: see stamp  BN/Use By: see stamp  BN/Use By: see stamp  BN/Use By: see stamp

Goldshield
Paracetamol
125mg
Suppositories
For rectal use only
MA Holder: Goldshield Pharmaceuticals Ltd.
10986/FL/A
PL 12762/0414

Goldshield
Paracetamol
125mg
Suppositories
For rectal use only
MA Holder: Goldshield Pharmaceuticals Ltd.
10986/FL/A
PL 12762/0414

Goldshield
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For rectal use only
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10986/FL/A
PL 12762/0414

Goldshield
Paracetamol
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Suppositories
For rectal use only
MA Holder: Goldshield Pharmaceuticals Ltd.
10986/FL/A
PL 12762/0414

Goldshield
Paracetamol
250mg
Suppositories
For rectal use only
MA Holder: Goldshield Pharmaceuticals Ltd.
10987/FL/A
PL 12762/0415

Goldshield
Paracetamol
250mg
Suppositories
For rectal use only
MA Holder: Goldshield Pharmaceuticals Ltd.
10987/FL/A
PL 12762/0415

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