Public Assessment Report

Paracetamol 500mg Capsules

PL 00418/0047
PL 00418/0056
PL 00418/0057
PARACETAMOL 500MG CAPSULES

PL 00418/0047
PL 00418/0056
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PARACETAMOL 500MG CAPSULES

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Peter Black Healthcare Limited Marketing Authorisations (licences) for the medicinal product Paracetamol 500mg Capsules (PLs 00418/0047, 0056-7). Paracetamol 500mg Capsules is used in the treatment of painful and feverish conditions.

PL 00418/0047 is a general sale list [GSL] medicine, PL 00418/0056 is a pharmacy [P] medicine and PL 00418/0057 is a prescription only medicine [POM].

These are applications for duplicate licences that cross-refer to data supporting the approved product; Paracetamol Capsules 500mg (PL 01932/0025).

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

The licences for these products were cancelled on 29 June 2006.
PARACETAMOL 500MG CAPSULES

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted marketing authorisations for the medicinal product Paracetamol 500mg Capsules (PLs 00418/0047, 0056-7) to Peter Black Healthcare Limited on 16 June 2006. PL 00418/0047 is a general sale list [GSL] medicine, PL 00418/0056 is a pharmacy [P] medicine and PL 00418/0057 is a prescription only medicine [POM].

These applications were submitted as simple abridged applications according to Article 4.8(a)(i) of Directive 65/65/EC, cross-referring to Paracetamol Capsules 500mg (PL 01932/0025)

The active ingredient paracetamol is an antipyretic analgesic. The mechanism of action is probably akin to that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

No new data were submitted for these simple applications, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

Paracetamol Capsules are recommended for the treatment of headaches, including migraine and tension headaches, and also for backache, rheumatic and muscle pain, period pain, ‘nerve pains’, toothache and for relieving the fever, aches and pains of colds and flu.

The marketing authorisations for these products were cancelled on 29 June 2006.
PHARMACEUTICAL ASSESSMENT

LICENCE No: PLs 00418/0047, 0056, 0057
PRODUCT NAME: Paracetamol Capsules 500 mg
COMPANY NAME: Peter Black Healthcare Limited
ACTIVE: Paracetamol Ph.Eur.
LEGAL STATUS: GSL, P, POM

INTRODUCTION

This is a simple abridged application that was submitted under Directive 65/65/EEC, Article 4.8(a)(i) for a product claimed to be identical to PL 01932/0025 Paracetamol Capsules 500 mg, first granted to Seven Seas Ltd on 1 January 1998 when PL 00071/0413 was taken over. PL 01932/0025 was renewed on 26 January 2000. A letter of access has been provided by Seven Seas Ltd.

COMPOSITION

The stated composition is identical to that specified for the cross-referenced product, PL 01932/0025 Paracetamol Capsules 500 mg, marketed in the UK.

METHOD OF PREPARATION

The method of manufacture is unchanged from that specified for the cross-referenced product, PL 01932/0025 Paracetamol Capsules 500 mg, marketed in the UK.

CONTROL OF STARTING MATERIALS

Active substance

The proposed Drug Substance Specification complies with requirements included in the Ph.Eur. monograph for Paracetamol.

Other ingredients

Qualitative and quantitative details of stated excipients are as specified for the cross-referenced product, PL 01932/0025 Paracetamol Capsules 500 mg, marketed in the UK.

TSE status

It has been confirmed that magnesium stearate is not derived from animal origins.

Current Ph.Eur. TSE Certificates for gelatin have been submitted.

CONTROL TESTS ON THE FINISHED MEDICINAL PRODUCT

Specifications and routine tests

The proposed Finished Product Specification is identical to that specified for the cross-referenced product, PL 01932/0025 Paracetamol Capsules 500 mg, marketed in the UK.
STABILITY

Stability tests on active substances

No new stability data have been provided or required.

Stability tests on the finished medicinal product

No new stability data have been provided or required. A shelf life of 60 months was previously justified for the cross-referenced product, PL 01932/0025 Paracetamol Capsules 500 mg, marketed in the UK.

No special storage requirements are required.

BIOAVAILABILITY/BIOEQUIVALENCE

These applications refer to data submitted in respect of the reference licence and no new data were provided. This is acceptable.

EXPERT REPORT

The Pharmaceutical Expert Statement provided confirmation that the chemistry and pharmaceutical particulars of the proposed product are as specified for the cross-referenced product, PL 01932/0025 Paracetamol Capsules 500 mg, marketed in the UK.

PRODUCT NAME AND APPEARANCE
SUMMARY OF PRODUCT CHARACTERISTICS
PATIENT INFORMATION LEAFLET
LABELLING

Satisfactory.

CONCLUSION

A product licence may be granted.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for applications of this type.
CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.
OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for these applications are consistent with those previously assessed for the cross-referenced product and as such have 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 a previously granted application for Paracetamol Capsules 500mg.

No new or unexpected safety concerns arose from these applications.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-referenced product.

RISK-BENEFIT ASSESSMENT

The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-referenced product. Extensive clinical experience with the active ingredient paracetamol is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.
## STEPS TAKEN FOR ASSESSMENT

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<tr>
<td><strong>1</strong></td>
<td>The MHRA received the marketing authorisation applications for Paracetamol 500mg Capsules on 16 July 2001.</td>
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<tr>
<td><strong>2</strong></td>
<td>The MHRA’s assessment of the submitted data was completed on 23 October 2001.</td>
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<td><strong>3</strong></td>
<td>Further information was requested from the company on 8 November 2001, 18 November 2002, 30 March 2006 and 13 June 2006.</td>
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<td><strong>4</strong></td>
<td>The applicant’s response to further information requests were received on 4 December 2002, 23 July 2003, 12 August 2003, 29 September 2003, 3 April 2006 and 13 June 2006.</td>
</tr>
<tr>
<td><strong>5</strong></td>
<td>The application was determined on 16 June 2006.</td>
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PARACETAMOL 500MG CAPSULES

PL 00418/0047
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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
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<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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<tr>
<td>29-06-06</td>
<td>Cancellation</td>
<td>Cancellation of licence</td>
<td>Approved.</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1. Trade Name of the Medicinal Product
Paracetamol 500 mg Capsules

2. Qualitative and Quantitative Composition
Each capsule contains Paracetamol 500 mg
For excipients, see 6.1

3. Pharmaceutical Form
Capsule, hard
Hard gelatin capsule with red coloured cap and white body imprinted with ‘Paracetamol’, and containing a white granular powder.

4. CLINICAL PARTICULARS
4.1. Therapeutic Indications
Paracetamol Capsules are recommended for the treatment of headaches, including migraine and tension headaches also for backache, rheumatic and muscle pain, period pain, ‘nerve pains’, toothache and for relieving the fever, aches and pains of colds and flu.

4.2. Posology and Method of Administration
For oral administration only.
Adults and Elderly: 2 Capsules up to four times a day.
These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.
Children: Not recommended for children under 12 years of age.

4.3. Contra-indications
Hypersensitivity to paracetamol and/or other constituents.
4.4. Special Warnings and Precautions for Use

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

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

Patient Information 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.

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.

4.5. Interactions with other Medicaments and other forms of Interaction

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

The anti coagulant 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

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

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

4.7. Effects on Ability to Drive and Use Machines

None
4.8. Undesirable Effects

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

4.9. Overdose

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g 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 arrhythmia’s 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

Paracetamol is an antipyretic analgesic. The mechanism of action is probably akin to that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

5.2. Pharmacokinetic Properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma protein is variable: 20 to 50% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% of the drug may be recovered in the urine within the first day. However, practically, no paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

5.3. Preclinical Safety Data

There are no preclinical data of relevance to the prescriber which are additional to that already updated in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Starch Maize
Magnesium Stearate

Capsule shell
Titanium Dioxide (E171)
Erythrosine (E127)
Quinoline Yellow (E104)
Patent Blue V (E131)
Gelatin
Shellac
N-Butyl Alcohol
Purified Water
Soya Lecithin
6.2. **Incompatibilities**

None

6.3. **Shelf Life**

60 months

6.4. **Special Precautions for Storage**

None

6.5. **Nature and Contents of Container**

Child resistant blister packaging composed of 250 micron uPVC/PVDC coating (base material) and 30 micron hard temper aluminium foil with ‘pyramid style’ emboss/compatible heat seal (lidding material) packed in a cardboard carton containing 6, 12 and 16 capsules.

6.6. **Instruction for Use/Handling**

Not applicable

7. **Marketing Authorisation Holder**

Peter Black Healthcare Limited
William Nadin Way
Swadlincote
Derbyshire
DE11 0BB

8. **Marketing Authorisation Number**

PL 00418/0047
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
16/06/2006

10 DATE OF REVISION OF THE TEXT
16/06/2006
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Paracetamol 500mg Capsules

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

3. PHARMACEUTICAL FORM
Capsule, hard
Hard gelatin capsule with red coloured cap and white body imprinted with ‘Paracetamol’, and containing a white granular powder.

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
Paracetamol Capsules are recommended for the treatment of headaches, including migraine and tension headaches also for backache, rheumatic and muscle pain, period pain, ‘nerve pains’, toothache and for relieving the fever, aches and pains of colds and flu.

4.2. Posology and method of administration
For oral administration only.

Adults and Elderly: 2 Capsules up to four times a day.
These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

Children: Not recommended for children under 12 years of age.

4.3. Contraindications
Hypersensitivity to paracetamol and/or other constituents.
4.4. Special warnings and precautions for use

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

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

Patient Information 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.

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.

4.5. Interactions 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

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

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

4.7. Effects on ability to drive and use machines

None.

4.8. Undesirable effects

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

4.9. Overdose

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g 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 arrhythmia’s 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

Paracetamol is an antipyretic analgesic. The mechanism of action is probably akin to that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

5.2. Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma protein is variable: 20 to 50% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% of the drug may be recovered in the urine within the first day. However, practically, no paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already updated in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Starch Maize
Magnesium Stearate

Capsule shell
Titanium Dioxide (E171)
Erythrosine (E127)
Quinoline Yellow (E104)
Patent Blue V (E131)
Gelatin
Shellac
N-Butyl Alcohol
Purified Water
Soya Lecithin
Antifoam DC 1510
IMS 74 OP BP
Black Iron Oxide (E172)
6.2. **Incompatibilities**

None.

6.3. **Shelf life**

60 months.

6.4. **Special precautions for storage**

None

6.5. **Nature and contents of container**

Child resistant blister packaging composed of 250 micron uPVC/PVDC coating (base material) and 30 micron hard temper aluminium foil with ‘pyramid style’ emboss/compatible heat seal (lidding material) packed in a cardboard carton containing 24 and 32 capsules.

6.6. **Instruction for use and handling (use, and disposal)**

Not applicable.

7. **MARKETING AUTHORISATION HOLDER**

Peter Black Healthcare Limited  
William Nadin Way  
Swadlincote  
Derbyshire  
DE11 0BB

8. **MARKETING AUTHORISATION NUMBER**

PL 0418/0056
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/06/2006

10 DATE OF REVISION OF THE TEXT

16/06/2006
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Paracetamol 500mg Capsules

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

3. PHARMACEUTICAL FORM
Capsule, hard
Hard gelatin capsule with red coloured cap and white body imprinted with ‘Paracetamol’, and containing a white granular powder.

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
Paracetamol Capsules are recommended for the treatment of headaches, including migraine and tension headaches also for backache, rheumatic and muscle pain, period pain, ‘nerve pains’, toothache and for relieving the fever, aches and pains of colds and flu.

4.2. Posology and method of administration
For oral administration only.

Adults and Elderly: 2 Capsules up to four times a day.
These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

Children: Not recommended for children under 12 years of age.

4.3. Contraindications
Hypersensitivity to paracetamol and/or other constituents.
4.4. Special warnings and precautions for use

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

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

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feel well, because of the risk of delayed, serious liver damage.

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severe hepatic impairment. The hazards of overdose are greater in those with (non-
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have no significant effect.

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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.

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

None.

4.8. Undesirable effects

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

4.9. Overdose

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g 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 arrhythmia’s 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.

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5.3. Preclinical safety data
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6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
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Magnesium Stearate

Capsule shell
Titanium Dioxide (E171)
Erythrosine (E127)
Quinoline Yellow (E104)
Patent Blue V (E131)
Gelatin
Shellac
N-Butyl Alcohol
Purified Water
Soya Lecithin
Antifoam DC 1510
IMS 74 OP BP
Black Iron Oxide (E172)
6.2. **Incompatibilities**

None.

6.3. **Shelf life**

60 months.

6.4. **Special precautions for storage**

None

6.5. **Nature and contents of container**

Child resistant blister packaging composed of 250 micron uPVC/PVDC coating (base material) and 30 micron hard temper aluminium foil with ‘pyramid style’ emboss/compatible heat seal (lidding material) packed in a cardboard carton containing 48, 60 and 96 capsules.

6.6. **Instruction for use and handling (, and disposal)**

Not applicable.

7. **MARKETING AUTHORISATION HOLDER**

Peter Black Healthcare Limited
William Nadin Way
Swadlincote
Derbyshire
DE11 0BB

8. **MARKETING AUTHORISATION NUMBER**

PL 0418/0057
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PARACETAMOL 500MG CAPSULES

PL 00418/0047
PL 00418/0056
PL 00418/0057

PATIENT INFORMATION LEAFLET

PARACETAMOL 500mg CAPSULES

PLEASE READ THIS LEAFLET CAREFULLY BEFORE TAKING PARACETAMOL 500mg CAPSULES

This leaflet will give you some important information about your medicine. Please read it carefully before you start taking Paracetamol 500mg Capsules. If there is anything you do not understand, please ask your Doctor or Pharmacist. Keep this leaflet safe, you may want to read it again.

Your medicine

Your medicine is in the form of a red and white capsule printed with the word 'Paracetamol'. Each capsule contains 500mg of the active ingredient Paracetamol. Each capsule also contains the inactive ingredients Maize Starch and Magnesium Stearate. The capsule shell contains Gelatin, Titanium Dioxide (E171), Erythrosine (E127), Patent Blue (E131) and Quinoline Yellow (E104). The printing ink contains Purified Water, Soya Lecithin, N-Buthyl Alcohol, Dimethyl Polyolsxoxane and Black Iron Oxide (E172), Shellac and BSS 74 O.P.

Paracetamol 500 mg Capsules are available in packs of 6, 12, 16, 24, 32, 48, 60 and 96 capsules. Pack sizes of 24 and 32 Paracetamol 500 mg Capsules can only be purchased from your pharmacist. Pack sizes of 48, 60 and 96 Paracetamol 500 mg Capsules can only be obtained on prescription from your pharmacist.

The Product Licence Holder for Paracetamol 500mg Capsules is Peter Black Healthcare Ltd. William Nadin Way, Swadlincote, Derbyshire DE11 0BB.
The Manufacturer for Paracetamol 500mg Capsules is Penta UK Ltd, William Nadin Way, Swadlincote, Derbyshire DE11 0BB.

What is your medicine used for?

Your capsules contain Paracetamol which is a type of 'analgesic' (painkiller) and can be used to relieve mild to moderate pain including headache, migraine, neuralgia, backache, toothache, sore throat, period pain, aches and pains. It can also relieve rheumatic aches and pains, influenza, feverishness and feverish colds.

Before taking your medicine

Make sure it is safe for you to take Paracetamol 500mg Capsules. If you answer YES to any of the following questions, or you are not sure about your answer, tell your doctor or pharmacist. If you don't, this medicine may make your condition worse:

• Have you ever been allergic to Paracetamol or any of the other ingredients listed?
• Have you had severe kidney or liver problems including alcoholic liver disease?
• Are you pregnant or breast-feeding?
• Are you taking any other medicines particularly those containing Paracetamol.

Are you taking other prescribed medicines, including warfarin (for thinning the blood), metoclopramide or domperidone (for nausea and vomiting), or cholestyramine (to lower the blood lipids)?
PARACETAMOL 500MG CAPSULES

PL 00418/0047
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Taking your medicine

Adults and children over 12 years: Take 2 capsules up to 4 times a day. These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.
Do not give to children under 12 years of age.
If you miss a dose of Paracetamol 500mg Capsules, do not worry - take your next dose at the usual time. Do not take extra capsules when it is time for your next dose to make up for the capsules you have missed. If you are unsure, ask your doctor or pharmacist.

What should you do 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.

Does your medicine have any unwanted effects?
Most people taking this medicine will find that it causes no problems. Very occasionally it has been known to cause skin rashes, or some blood disorders. If you experience any of these effects or any other symptoms, consult your doctor or pharmacist.

Storage and disposal of your medicine
Do not take these capsules after the expiry date printed on the pack.
Keep out of sight and reach of children - it could be harmful to them.

Remember
If you have any questions, more information is available from your doctor or pharmacist.

Date of Leaflet preparation: April 2006

Product Licence Nos: 0418/0047, 0418/0056 & 0418/0057
PARACETAMOL 500MG CAPSULES
PL 00418/0047

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Paracetamol 500 mg Capsules are available in packs of 16 and 32 capsules. You can only buy packs of 32 capsules from your pharmacist.
The Product Licence Holder for Paracetamol 500mg Capsules is Peter Black Healthcare Ltd, William Nadin Way, Swadlincote, Derbyshire DE11 0BB.
The Manufacturer for Paracetamol 500mg Capsules is Perrigo UK Ltd, William Nadin Way, Swadlincote, Derbyshire DE11 0BB.

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**Date of Leaflet preparation: April 2006**

Product Licence No: 0418/0047
Labelling
PARACETAMOL 500MG CAPSULES

PL 00418/0047
PL 00418/0056
PL 00418/0057

Generic Blister Foil

Batch Number & Expiry Date is embossed at the time of manufacture
PARACETAMOL 500MG CAPSULES

PL 00418/0047
PL 00418/0056
PL 00418/0057

Braille template