SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paraserts 250mg Suppositories

Paracetamol 250mg Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains paracetamol 250mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppositories.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain and fever, for example, headache, toothache, earache, sore throat, and aches and pains associated with colds and influenza.

Paraserts Suppositories may be especially useful in patients having difficulty taking oral forms of paracetamol, e.g. patients with nausea and vomiting.

4.2 Posology and method of administration

Method of administration: Rectal

Children aged 6 to 12 years:

6 to 9 years: 1 suppository every 4 to 6 hours.

10 to 12 years: 1-2 suppositories every 4 to 6 hours.

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 pharmacist or doctor**.**

Only whole suppositories should be administered – do not break the suppository before administration.

4.3 Contraindications

Hypersensitivity to paracetamol, or to any of the excipients listed in section 6.1.

Paraserts Suppositories contain soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

4.4 Special warnings and precautions for use

Paraserts 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).

The label and leaflet contain the following statements:

Label:

CONTAINS PARACETAMOL

Do not give more medicine than the label tells you to. If your child does not get better, talk to a doctor

Do not give anything else containing paracetamol while giving this medicine

Talk to a doctor at once if your child uses too much of this medicine, even if they seem well.

Leaflet:

Talk to a doctor at once if your child uses too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

4.5 Interaction with other medicinal products and other forms of interaction

The absorption of paracetamol is increased by metoclopramide 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.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risk factors (see section 4.4).

4.6 Fertility, pregnancy and lactation

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

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

Adverse drug reactions (ADRs) are listed below by System Organ Class (SOC).

The frequencies are defined according to the following convention:

Very common	≥ 1/10
Common	≥ 1/100 to <1/10
Uncommon	≥ 1/1,000 to <1/100)
Rare	≥ 1/10,000 to <1/1,000
Very rare	<1/10,000

System Organ Class	Frequency	Adverse Drug Reaction
Blood and lymphatic system disorders	Not known	Blood disorder (including thrombocytopenia and agranulocytosis)[1]
Immune system	Very rare	Anaphylactic reaction

disorders	Very rare	Hypersensitivity
Hepatobiliary disorders	Not known	Liver injury[2]
Skin and subcutaneous tissue disorders	Very rare Not known Not known Not known	Rash Fixed eruption Rash pruritic Urticaria
Renal and urinary disorders	Rare	Increase in creatinine (mostly secondary to hepatorenal syndrome)
Investigations	Not known	Transaminases increased[3]
Metabolism and nutrition disorders	Not known	High anion gap metabolic acidosis
General disorders and administration site conditions	Common	Anorectal erythema

[1] Reported following paracetamol use, but not necessarily causally related to the drug

[2] Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year

[3] Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol; these elevations are not accompanied with liver failure and usually resolve with continued therapy or discontinuation of paracetamol.

Very rare cases of serious skin reactions have been reported.

Description of selected adverse reactions

High anion gap metabolic acidosis

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.go.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 arrythmias 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

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

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 30ºC

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

Amdeepcha Limited
85 Yarmouth Road, Blofield
Norwich, Norfolk NR13 4LQ, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 19255/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/11/2011

10 DATE OF REVISION OF THE TEXT

07/01/2026

11 DOSIMETRY (IF APPLICABLE)

Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable