SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Para-Supps Paracetamol 500 mg Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 500 mg of paracetamol.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository

White to ivory-coloured, torpedo-shaped, about 26 mm in length

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of mild to moderate pain and fever in adults and children.

Suppositories are 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

Para-Supps Paracetamol Suppositories are for rectal administration.

The dosage should be based on age and weight. The normal dose should approximate 15 mg/kg body weight to a maximum of 60 mg/kg/day, e.g.

Adults: 500-1000 mg (1-2 suppositories) to a maximum of 8 in 24 hours

Children 12-16 years: 500-1000 mg (1-2 suppositories) to a maximum of 6 in 24 hours

Do not use more than 4 doses in any 24-hour period. Leave at least 4 hours between doses. The recommended dose should not be exceeded. Only whole suppositories should be administered.

4.3 Contraindications

Para-Supps Paracetamol 500 mg Suppositories should not be used by patients with known hypersensitivity to paracetamol or to any other ingredient of the suppositories.

4. 4 Special Warnings and Special Precautions for Use

Para-Supps Paracetamol 500 mg Suppositories should not be combined with other analgesic medications containing paracetamol.

Para-Supps Paracetamol 500 mg Suppositories should be given with care in patients with impaired liver or kidney function

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

The following warnings are required on the label:

- Do not use more medicine than the label tells you to. If you or your child does not get better, talk to your doctor
- Do not use anything else containing paracetamol while taking this medicine
- Talk to a doctor at once if you or your child takes too much of this medicine, even if you or your child feels well

The following warning is required in the leaflet:

- Talk to a doctor at once if you or your child takes too much of this medicine even if you or your child feels well. This is because too much paracetamol can cause delayed, serious liver damage

4.5 Interaction with other medicinal products and other forms of interaction

Drugs that induce hepatic microsomal enzymes such as alcohol, barbiturates and other anticonvulsants, may increase the hepatotoxicity of paracetamol, particularly after overdosage.

The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding. The effect appears to increase as the dose of paracetamol is increased, but can occur with doses as low as 1.5-2.0 g paracetamol per day for 5-7 days. Occasional doses have no significant effect.

Enzyme-inducing medicines, such as some anti-epileptic drugs (phenytoin, phenobarbital, carbamazepine) have been shown in pharmacokinetic studies to reduce the plasma AUC of paracetamol by approximately 40%. Other substances with enzyme-inducing properties, eg rifampicin and St John's wort (hypericum), are also suspected of causing lowered concentrations of paracetamol. In addition, the risk of liver damage during treatment with the 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 a clinically significant amount. Available published data do not contraindicate breast-feeding.

4.7 Effects on ability to drive and use machines

None likely

4.8 Undesirable effects

Side-effects at therapeutic doses are rare.

Frequency	System Organ Class	Adverse Event
Common (>1/100 to <1/10)	Miscellaneous	Redness of the rectal mucous membranes
Rare (>1/10,000 to <1/1,000)	General	Allergic reactions
	Skin	Exanthema, urticaria
	Liver	Liver damage
	Genitourinary	Increase in creatinine (mostly secondary to hepatorenal syndrome)

There have been reports of blood dyscrasias, including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

Hepatic necrosis may occur after overdosage (see below).

4.9 Overdose

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion and clinical symptoms generally culminate after 4-6 days.

Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

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. Administration of oral methionine or intravenous N-acetylcysteine, which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available.

Toxicity: 5 g during 24 hours in a child aged 3½ years or 15-20 g in adults may cause fatal intoxication. The toxic dose for children and adults is generally > 140 mg/kg. Malnutrition, dehydration, medication with enzyme-inducing drugs such as some anti-epileptic drugs (phenytoin, phenobarbital, carbamazepine), rifampicin and St. John's wort (hypericum) are risk factors, and even slight overdosage can then cause marked liver damage. Even subacute “therapeutic” overdose has resulted in severe intoxication, with doses varying from 6 g/24 hours for a week, 20 g for 2-3 days, etc.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code N02B E01

Paracetamol is an aniline derivative with analgesic and antipyretic actions similar to those of aspirin but with no demonstrable anti-inflammatory activity. Paracetamol is less of an irritant to the stomach than aspirin. It does not affect thrombocyte aggregation or bleeding time. Paracetamol is generally well tolerated by patients hypersensitive to acetylsalicylic acid.

5.2 Pharmacokinetic properties

Paracetamol is well absorbed after both oral and rectal administration. Peak plasma concentrations are reached within 2 to 3 hours after rectal administration. The plasma half-life is about 2 hours.

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

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the SPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hard fat
Soya lecithin

6.2 Incompatibilities

None

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 25° C. Keep in the outer carton.

6.5 Nature and contents of container

Para-Supps Paracetamol 500 mg suppositories are available in LDPE-coated aluminium foil strips in packs containing 10 suppositories.

6.6 Special precautions for disposal

The blister should be opened immediately before use.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 19255/0003

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