SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains Paracetamol 125, 150, 250, 300mg
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

Adults:

The usual dose for adults, elderly and children 12-18 years s till 1000 mg every four hours up to a maximum of 4000 mg every day

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 you are not sure, ask your doctor or pharmacist.

How many Paracetamol Suppositories to give your child

- Paracetamol Suppositories are for children aged from 3 months to 5 years.
- The number of suppositories to give your child depends on their age and weight.
- The usual dose is one or two suppositories.
- You should ask your child's doctor or pharmacist for advice on how many suppositories to give. You must leave at least 6 hours between each dose.

If you are not sure how many suppositories to give your child, don't guess. Ask your child's doctor or pharmacist for advice.
Do not give your child more suppositories than stated in the table below.
The lowest number of applications per day is intended for the youngest children in a specific group.
Contact your child's doctor if your child's symptoms get worse or do not improve.

Age (years)	Body Weight (kg)	Dose (mg)	Number of doses
0.25 -1	5.5-10	125 (=1 suppository)	1-3 times per 24 hours
1-2	10-12.5	250 (=2 suppositories)	2-3 times per 24 hours
2-4	12.5-17	250 (=2 suppositories)	3 times per 24 hours
4-6	17-22	250 (=2 suppositories)	4 times per 24 hours

In children below the age of 4 years use for more than 2 days is not recommended without consulting a doctor.
If pain persists for more than 5 days or fever for more than 3 days or gets worse, or if there are other symptoms occur, treatment should be discontinued and a doctor should be consulted.

1. 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.
2. You may find it easier to give your child the suppository if they are lying on their front or side on a bed. Do whichever is more comfortable for your child.
3. Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.

4. Gently push the suppository into your child's back passage (rectum) with the pointed end first. Then wash your hands.
   Try to keep your child still for a minute or two.
5. If your child needs to be given another suppository, remove another one from the wrapper. Then insert it into your child's back passage as before. Once again you should try to keep your child still for a minute or two. Then wash your hands.

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, es
pecially with combinations of more than one pain killing active ingredient, can lead to permanent kidney damage with the risk of liver failure (analgesic nephropathy).

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.

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

Common
Miscellaneous:
Redness of the rectal mucous membranes
>1/100
Rare
General:
Allergic reactions including skin rashes
<1/1000
Skin:
Exanthema, urticaria
Liver:
Liver damage
Genitourinary:
Increase in creatinine (mostly secondary to hepatorenal syndrome)
There have been some reports of blood dyscrasias including thrombocytopenia and argranulocytosis, 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 arrythmias and pancreatitis have been reported.

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 producesanalgesia 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

Semisynthetic glycerides

6.2 Incompatibilities

None relevant

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 30ºC

6.5 Nature and contents of container

PVC-Blister packet

7 MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorization Holder
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