SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 80mg Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 80mg Paracetamol

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suppository

White, torpedo shaped, suppository

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain and fever in babies and children from the age of 3 months.

Paracetamol suppositories may be especially useful in patients unable to take oral forms of paracetamol e.g. Post-operative patients or patients with nausea and/or vomiting.

4.2 Posology and method of administration

For rectal use only

Dosage should be based on the child's weight, with a recommended dosage of 15mg/kg per administration. Ages presented below are provided as an accompanying guide only.

3 – 12 months (5kg): One suppository

This dose 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. The product should not be used for more than 3 days, except on the advice of a doctor. Higher doses do not produce any

increase in analgesic effect. Only whole suppositories should be administered – do not break the suppository before administration.

Hepatic / renal dysfunction
Caution should be exercised when administering the product to patients with severe hepatic or renal impairment.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Paracetamol suppositories should not be combined with other analgesic medications that contain paracetamol.

Paracetamol suppositories should be administered with care to patients with impaired kidney or liver function.

The hazards of overdose are greater in those with non-cirrhotic liver disease.

Label and leaflet should state the following warnings:

Label

Do not exceed the stated dose.

If symptoms persist consult your doctor.

Keep out of the reach and sight of children.

Leave at least 4 hours between doses.

Immediate medical advice should be sought in the case of an overdose, even if the child seems well.

Do not give with 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 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.

Drugs which induce hepatic microsomal enzymes such as alcohol, barbiturates and other anticonvulsants, may increase the hepatotoxicity of paracetamol, particularly after over-dosage. 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 Fertility, pregnancy and lactation

Fertility: There are no data on the effects of paracetamol suppositories on human fertility. Fertility was unaffected following paracetamol treatment in animal studies (see section 5.3).
Pregnancy: 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.
Lactation: 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 known.

4.8 Undesirable effects

Adverse drug reactions are rare.

Common	≥1/100 to <1/10	Miscellaneous	Redness or soreness of the rectal mucous membrane
Rare	≥1/10,000 to <1/1,000	General	Allergic reactions
		Skin	Exanthema, urticaria
		Liver	Liver damage

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

Hepatic necrosis may occur after paracetamol overdose (see Section 4.9).

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).

Risk factors

If the patient

Is on long term treatment with carabamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

Regularly consumes ethanol in excess of recommended amounts.

Or

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 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.

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.

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 h ospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the 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 center.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations occur about 2 to 3 hours after rectal administration. Usual analgesic doses produce total serum concentrations of 5 to 20mcg/ml. 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.

Paracetamol is excreted in the urine mostly as metabolites; 2-4% is excreted unchanged. The average elimination half life is 1 to 4 hours; half life is slightly prolonged in neonates (2.2 to 5 hours) and in cirrhotics.

The overall elimination rate constant for paracetamol in children, from birth to 12 years of age, is the same as for adults but neonates have diminished capacity to form glucuronide conjugates of paracetamol.

5.3 Preclinical safety data

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

Hard fat

Macrogol cetostearyl ether

Glyceryl ricinoleate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and contents of container

Ten suppositories packed in white/opaque PVC/PE film.

Each suppository is packed separately. Due to the perforations of the welds an individual suppository can be torn out.

Two strips, each containing five suppositories, are packed into a cardboard carton.

6.6 Special precautions for disposal and other handling

The suppository should only be removed from the blister packaging immediately before use.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs

Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee
Co. Meath
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1113/4/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 2012

10 DATE OF REVISION OF THE TEXT

December 2013