Emzor Paracetamol 125mg Dispersible Tablet

1. Name of the medicinal product

Paracetamol 125 mg Tablet

2. Qualitative and quantitative composition

Each Tablet contains paracetamol 125 mg. For the

full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet.

4. Clinical particulars

Therapeutic indications

For the treatment of mild to moderate pain and fever. Emzor/Paracetamol Tablet may be especially useful in patients unable to take oral forms of paracetamol, e.g. post-operatively or with nausea and vomiting.

Posology and method of administration

Method of administration: rectal

Children:

1 year – 5 years: 1 -2 Tablet every 4 to 6 hours. Dosages

should be based on the child's age and weight i.e.: 1 year

(10 kg) – 125 mg (1 Tablet)

5 years (20 kg) – 250 mg (2 Tablet)

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 doctor**.** Only whole Tablet should be administered – do not break the Tablet before administration

Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, soy or peanuts.

Special warnings and precautions for use

Emzor/Paracetamol Tablet 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).

Label and leaflet will state the following warnings:

Label:

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

“ Do not give with any 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.”

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

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, especially in patients with risk factors (see section 4.4).

Fertility, 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.

Effects on ability to drive and use machines

None known.

Undesirable effects

Common >1/100	*Miscellaneous:*	Redness of the rectal mucous membranes
Rare <1/1000	*General:* *Skin:* *Liver:* *Genitourinary:*	Allergic reactions including skin rashes Exanthema, urticaria Liver damage 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.

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.

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).

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

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

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 thresholdand antipyresis through action on the hypothalamic heat-regulation centre.

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 cystein and mercapturic acid derivatives.

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

List of excipients

Hydrogenated fat

Soyabean lecithin

Incompatibilities

None relevant.

Shelf life

36 months.

Special precautions for storage

Do not store above 30° C.

Nature and contents of container

PVC blister packet.

In pack size of 10 Tablet.

Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

Emzor Pharma Ind. Ltd