Paracetamol Extended Release Tablet

Sumo-L 650 ER

ALKEM

1. NAME OF THE MEDICINAL PRODUCT

Sumo-L 650 ER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each extended release tablet contains:
Paracetamol IP……650 mg

3. PHARMACEUTICAL FORM

Extended release tablet for oral administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of mild to moderate pain and febrile conditions, *eg* headache, toothache, colds, influenza, rheumatic pain and dysmenorrhoea.

4.2 Posology and Method of Administration

Posology

Adults including elderly and children over 12 years: Two tablets every 8 hours, to a maximum of 6 tablets daily in divided doses. Tablet to be swallowed whole – should not be crushed, chewed, split or dissolved.
Children under 12 years: Not recommended for children under 12 years of age. Alternative presentations of paracetamol are recommended for paediatric usage in order to obtain suitable doses.

Method of administration

For oral administration.

4.3 Contraindications

Hypersensitivity to Paracetamol or any of the other constituents.

4.4 Special Warnings and Special Precautions for Use

Where analgesics are used long-term (>3 months) with administration every two days or more frequently, headache may develop or worsen. Headache induced by overuse of analgesics (MOH medication-overuse headache) should not be treated by dose increase. In such cases, the use of analgesics should be discontinued in consultation with the doctor.

Care is advised in the administration of paracetamol to patients with alcohol dependency (see section 4.9), severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Label Warnings:

- Do not exceed the recommended dose
- If symptoms persist consult your doctor
- Keep out of the reach and sight of children
- Do not take with any other paracetamol-containing products.
- Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Anticoagulants - the 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.
- Metoclopramide – may increase speed of absorption of paracetamol.
- Domperidone – may increase speed of absorption of paracetamol.
- Colestyramine – may reduce absorption if given within one hour of paracetamol.
- Imatinib - restriction or avoidance of concomitant regular paracetamol use should be taken with imatinib.

4.6 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 a clinically significant amount. Available published data do not contraindicate breast-feeding.

4.7 Effects on Ability to Drive and Use Machines

None

4.8 Undesirable Effects

Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality related to Paracetamol
Very rare cases of serious skin reactions have been reported.

4.9 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.
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 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, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within one 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 24 h from ingestion should be discussed with the NPIS or a liver unit.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Paracetamol has analgesic and antipyretic properties but it has no useful anti-inflammatory properties. Paracetamol's effects are thought to be related to inhibition of prostaglandin synthesis.

5.2 Pharmacokinetic Properties

Absorption: paracetamol is readily absorbed from the gastrointestinal tract.

Distrubution: peak plasma concentrations occur about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Metabolism: It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause tissue damage.

Elimination: It is excreted in the urine, mainly as the glucuronide and sulphate conjugates. The elimination half-life varies from about 1 to 4 hours.

5.3 Preclinical Safety Data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 Shelf-life

The expiry dates are indicated on the label and packaging.

6.2 Special Precautions for Storage

Store in a cool place, Protected from light

7. MARKETED BY

ALKEM

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Date of revision: November 2019