ALGORENS

Instructions for the medicinal product

Trade name: Algorens.
International Nonproprietary Name: Paracetamol.
Dosage form: Oral Solution.
Composition: Each 5 ml contains:
Paracetamol BP 125 mg.
Pharmacotherapeutic group: Other Analgesics and Antipyretics; Anilides.
ATC Classification: N02BE01.
Pharmacologic property:
Pharmacodynamics:
Analgesic – the mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain-impulse generation.
The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.
Antipyretic – paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulation centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.
Pharmacokinetics:
Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.
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 liver damage.
Indications for use:
Recommended for the relief of pains of teething, toothache and sore throats and for reducing fever often associated with colds and 'flu' and childhood infections such as chicken pox, whooping cough, measles and mumps.
Contraindications:
• Hypersensitivity to paracetamol or to propacetamol hydrochloride (prodrug of paracetamol) or to one of the excipients;
• Severe hepatocellular insufficiency or decompensated active liver disease.
Precautions: should be used with caution in cases of: hepatocellular insufficiency, severe renal insufficiency (creatinine clearance ≤ 30 mL/min), chronic alcoholism, chronic malnutrition (low reserves of hepatic gluthatione), and dehydration.
Pregnancy and Lactation:
Should be used during pregnancy after a careful benefit-risk assessment. In this case, the recommended posology and duration must be strictly observed.
After oral administration, paracetamol is excreted into breast milk in small quantities. No undesirable effects on nursing infants have been reported.
Dosage and directions for use:
Oral use.
The medicine is intended for use at children from 2 months up to 12 years of age.
Children 2 – 3 months:
Post-vaccination fever - 60 mg of solution. If necessary, after 4-6 hours, give a second 60 mg dose.
Other causes of pain and fever (only if weighs over 4 kg, born after 37 weeks) - 60 mg of solution. If necessary, after 4-6 hours, give a second 60 mg dose.
Do not give to babies less than 2 months of age. Do not give more than 2 doses. Leave at least 4 hours between doses. If further doses are needed, talk to your doctor.
Children 3 – 6 months: 10 mg/kg - 4 times in 24 hours.
Children 6 – 24 months: 120 mg - 4 times in 24 hours.
Children 2 – 4 years: 180 mg - 4 times in 24 hours.
Children 4 – 8 years: 240 mg - 4 times in 24 hours.
Children 8 – 10 years: 360mg - 4 times in 24 hours.
Children 10 – 12 years: 500 mg - 4 times in 24 hours.
Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. Do not give this medicine to your child for more than 3 days without speaking to your doctor
Renal insufficiency:
It is recommended, when giving paracetamol to patients with severe renal impairment (creatinine clearance ≤ 30 ml/min), to increase the minimum interval between each administration to 6 hours.
Hepatic insufficiency:
At patients with chronic or compensated active liver disease, especially in those with the hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), and dehydration, the maximum daily dose must not exceed 3 g.
Side-effects:
Adverse reactions to paracetamol are rare and serious reactions are very rare.
Blood and lymphatic system disorders: thrombocytopenia; neutropenia; leucopenia.
Gastrointestinal disorders: diarrhea, abdominal pain.
Hepatobiliary disorders: increased levels of liver enzymes.
Immune system disorders: anaphylactic shock; Quincke's edem; hypersensitivity reactions.
Laboratory examinations: decreased INR values; elevated INR values.
Skin and subcutaneous disorders: urticaria; erythema; rash.
Vascular disorders: hypotension (as symptom of anaphylaxis).
Overdose:
Symptoms: 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.
Treatment: 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.
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 hours from ingestion should be discussed with the NPIS or a liver unit.
Drug interaction:
Co-administration of phenytoin and paracetamol can lead to reduced paracetamol efficacy and increased risk of paracetamol hepatotoxicity. Patients receiving phenytoin should avoid high and/or chronic doses of paracetamol. Because of the risk of hepatotoxicity it is necessary to monitor patients.
Probenecid causes an almost 2-fold reduction in clearance of paracetamol by inhibiting its conjugation with glucuronic acid. A reduction of the paracetamol dose should be considered for concomitant treatment with probenecid.
Salicylamide may prolong the elimination t1/2 of paracetamol.
Caution should be paid to the concomitant intake of enzyme-inducing substances, such as barbiturates, isoniazid, carbamazepine, rifampicin and ethanol.
Paracetamol may enhance the effects of anticoagulants.
Cautions:
Do not give with any other paracetamol-containing products.
Never give more medicine than shown in the table
Do not give to babies less than 2 months of age.
For infants 2-3 months no more than 2 doses should be given.
Do not give more than 4 doses in any 24 hour period.
Leave at least 4 hours between doses.
Do not give this medicine to your child for more than 3 days without speaking to your doctor.
As with all medicines, if your child is currently taking any medicine consult your doctor before taking this product.
If symptoms persist, consult your doctor.
Prolonged use except under medical supervision may be harmful.
If your baby was born prematurely and is less than 3 months old consult your doctor prior to use.
Immediate medical advice should be sought in the event of an overdose, even if the patient feels well because of the risk of irreversible liver damage.
Presentation:
100 ml plastic bottle with spone dozator , plastic cap hollow spoon and label in a monocarton, insert enclosed.
Storage:
Keep in dry place, protected from light at a temperature below 30°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Non-prescribed medicine.

BELINDA

Manufactured for:
Branch of Apteki 36.6 Ltd.
Kabul, Afghanistan
Manufactured by:
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