PARAMAX

PARACETAMOL ORAL SUSPENSION BP

125 MG/5ML

COMPOSITION:

Each 5 ml contains:

Paracetamol BP	125 mg
Flavoured palatable base	q.s.
Colour: Tartrazine	

DESCRIPTION:

Paracetamol 125 mg/5 ml oral suspension is indicated in the treatment of mild to moderate pain.

INDICATION:

For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.

PHARMACOKINETICS:

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half-life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 50% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% of the drug may be recovered in the urine within the first day. However, practically no Paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

PHARMACODYNAMICS:

Pharmacotherapeutic group: Anilides

ATC code: N02BE01

Mechanism of action

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

POSOLOGY AND METHOD OF ADMINISTRATION:

For oral administration only

It is important to shake the bottle for at least 10 seconds before use.

Child's Age	How Much	How often (in 24 hours)
6 – 8 years	One 5 ml spoonful (large end)	4 times
8 – 10 years	One 5.0 ml spoonful (large end) and one 2.5 ml spoonful (small end)	4 times
10 – 12 years	Two 5 ml spoonfuls (large end)	4 times

- 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 with out speaking to your doctor or pharmacist
- Do not give to children under the age of 6 years.

Children aged 12-16 years: Two - three 5mL spoonfuls (large end) up to 4 times a day.

Adults and children over 16 years: Two - four 5mL spoonfuls (large end) up to 4 times a day

CONTRAINDICATION:

Hypersensitivity to paracetamol and/or other constituents.

Patients with severe hepatic dysfunction.

SPECIAL WARNING AND PRECAUTION FOR USE:

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

- Contains paracetamol.
- Do not give with any other paracetamol-containing products.
- For oral use only.
- Never give more medicine than shown in the table.
- Always use the spoon supplied with the pack. Do not overfill the spoon.
- 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 or pharmacist.
- As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.
- Do not store above 30°C. Protect from light. Store in the original package.
- 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.
- If symptoms persist consult your doctor.
- Keep out of the reach and sight of children.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

Drugs which induce hepatic microsomal enzymes such as alcohol. Concomitant barbiturates and tricyclic antidepressants may increase the hepatoxicity of Paracetamol particularly after overdose. Anti-convulsant or oral steroid contraceptives have the ability to reduce serum levels of Paracetamol by liver enzyme induction. The speed of absorption of Paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. 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.

PREGNANCY AND LACTATION:

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 clinically significant quantities. Available published data do not contraindicate breast feeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

None

ADVERSE REACTIONS:

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Very rare cases of serious skin reactions have been reported.

Cases of acute pancreatitis have been reported. Paracetamol has been widely used and reports of adverse reactions are rare, and are generally associated with overdosage.

Allergic reactions occur occasionally.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods. A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of the disease improved after paracetamol withdrawal.

Nephrotoxic effects are uncommon and have not been reported in association with therapeutic doses, except after prolonged administration.

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.

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.

Treatment with activated charcoal should be considered if the overdose has been taken within one 1 hour.

INCOMPATIBILITY:

Not known.

SHELF LIFE:

3 Years

PACKAGING:

100 ml amber coloured PET bottle is packed in a carton along with insert.

STORAGE CONDITION:

Store in dry place below 30°C. Protect from light & moisture.

Keep out of reach of children.

DISTRIBUTED BY:

Relief Pharma Ltd.

5th Street of Taimany, Kabul

Afghanistan.

MANUFACTURES BY:

Cian Health Care Pvt. Ltd.

Kh. No. : 248, Village Sisona, Bhagwanpur,

Roorkee, Haridwar, Uttarakhand, India.

Overseas Address:

Crossgate House, Cross Street,

Sale M44 9FT, United Kingdom.

DATE OF PUBLICATION: 01 March 2017