SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Paediatric Paracetamol Oral Solution BP 120 mg/5mL

BRAND NAME: PARAKANT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml (teaspoonful)contains:

Paracetamol BP……120 mg

In a flavoured syrupy base……q.s.

Colur: Carmoisine

3. PHARMACEUTICAL FORM:

Liquid Oral Dosage Form – Solution.

Pink coloured clear liquid.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Paracetamol oral solution is recommended for the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains, symptomatic relief of rheumatic aches and pains and of influenza, feverishness and feverish colds.

4.2 Posology and method of administration:

Infants 6 months - 1 year: 2.5 ml (half a medicine measure) every four hours.

Children 1 - 3 years: 5 ml (one medicine measure) every four hours.

Children over 5 years: 5 -10 ml (one to two medicine measures) every four hours.

Or as directed by physician.

Method of administration: For oral administration only.

4.3 Contraindications:

Hypersensitivity to the paracetamol or to any of the excipients used during formulation.

4.4 Warning and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose era greater in those with noncirrhotic alcohol liver disease.

Do not exceed the stated dose.

Do not take with any other paracetamol-containing products.

If symptoms persist for more than 3 days or get worse consult your doctor.

4.5 Drug Interactions

Cholestyremine: The speed of absorption of paracetamol is reduced by cholestyremine.

Metoclopramide and Domperidone: The absorption of paracetamol is increased by metoclopramide and domperidone.

Warfarin: The anticoagulant 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.

Chloramphenicol: Increased plasma concentration of chloremphenicol.

4.6 Fertility Pregnancy & 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 the 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:

It is safe to use medicine.

4.8 Adverse Effects

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

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

Risk Factors

If the patient

a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin 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 end 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, cerabral 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. 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.

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.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

ATC Code: N02BE01

Paracetamol has analgesic and anti-pyretic actions.

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 center to produce peripheral vasodilation resulting In Increased blood flow through the skin, 8W8a1lng and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties

Absorption and Fate

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion.

It is metabolized 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.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose (Sugar S-30), Propylene Glycol, Sorbitol 70%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Flavour Strawberry, Colour Carmoisine Supra IDACOL, Citric Acid Monohydrate, Purified Water.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special precautions for storage:

Store at a temperature not exceeding 30°C, in a dry place.

Protect from light.

Keep the medicine out of reach of children.

6.5 Nature and contents of container

60 ml / 100 ml Amber coloured Pet bottle with 25 mm cap in a carton along with insert.

7. APPLICANT
Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,
Vapi - 396 195. Gujarat, INDIA.

8. NATIONAL REGISTRATION NUMBER

07261/08228/REN/2021

9. DATE OF AUTHORISATION

11/04/2022

10. DATE OF REVISION OF THE TEXT

July 2023