

Acetamol Syrup 120mg/5ml

Name and Strength of Active Substance(s)

Paracetamol 120mg/5ml

Product Description

A clear orange colored syrup having orange flavor.

Pharmacodynamics

Paracetamol is a centrally acting analgesic and antipyretic with minimal anti-inflammatory properties.

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 sensitize pain receptors to mechanical or chemical stimulation

Antipyretic

Paracetamol act centrally on the hypothalamic heat-regulating centre to produce peripheral vasodilatation 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

Following oral administration paracetamol is rapidly absorbed.

Absorption:

Paracetamol absorption takes place mainly in the small intestine and therefore the rate of absorption is depending on the rate of gastric emptying. It has been shown that drugs which delay gastric emptying also delay the absorption of paracetamol. The presence of food in the stomach has also been reported to reduce the rate of absorption of paracetamol. Alterations in gastric pH have no appreciable effect on paracetamol absorption.

During absorption, the amount of paracetamol which is inactivated is negligible and it has been shown that paracetamol dose not affect gastric mucosal permeability and does not produce mucosal bleeding.

Peak plasma concentrations are reached 1 hour after absorption. The plasma half life is 1 to 3 hours.

Distribution:

Distributed into most body tissues; crosses the placenta and enters breast milk. Plasma protein binding: Approx 25%.

Metabolism:

Paracetamol is metabolized by the microsomal enzyme system of the liver. This metabolism is mainly to the glucuronide and sulphate conjugates, accounting for approximately 49% and 26% of the ingested dose respectively. About 4% is excreted as free paracetamol. Other minor pathways include the production of catechol derivatives and cysteine conjugates (via glutathione).

Excretion:

Paracetamol excretion is rapid and occurs via the urine. Elimination half-life: Approx 1-3 hr.

Indication

Indicated for the relief of fever, headache and symptoms of cold and flu, toothache, discomfort of teething and fever after vaccination.

Recommended Dosage

For an accurate dosing, weigh your child and work out the dosage to be given based on a 15mg of Paracetamol for every kg body weight given every 4 to 6 hours

eg: If your child weighs 20 kg: $20 \times 15 \text{ mg} = 300 \text{ mg} = (300\text{mg} / 120\text{mg} \times 5\text{ml}) = 12.5 \text{ ml}$

Maximum daily dose: 60mg/kg presented in divided doses of 10 - 15 mg/kg throughout the 24 hour period.

Child's Age	Child's Weight (kg)	How Much	How often (in 24 hours)
3 – 6 months	4	One 2.5 mL	4 times
6 – 24 months	8	One 5 mL	4 times
2 – 4 years	12	One 5.0 mL and one 2.5 mL	4 times
4 – 8 years	16	Two 5 mL	4 times
8 – 10 years	24	Three 5 mL	4 times
10 - 12 years	32	Four 5 mL	4 times

- Below 3 months: 5 to 10mg/kg (On doctor's advice only)
- Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.
- 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

Mode of Administration

Oral administration

Contraindications

Hypersensitivity to paracetamol or any of the other ingredients/components of the product
Severe and active hepatic impairment

Warnings and Precautions

This preparation contains PARACETAMOL.
Do not take any other paracetamol containing medicines at the same time.

- Do not take if allergic to paracetamol.
- Patients should contact their health care provider if symptoms persist (if the pain lasts for more than 10 days, if there is redness or fever lasts more than 3 days).
- Paracetamol should be given with care to patients with impaired kidney or liver function.
- Large doses should be avoided in patients with hepatic impairment. Paracetamol overdose may harm the liver.
- Do not exceed recommended dose.
- Paracetamol provides symptomatic relief only, additional therapy to treat the cause of the pain or fever should be instituted when necessary.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.

These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Effects on Ability to Drive and Use Machines

It is unlikely to impair a patient's ability to drive or use machinery.

Interactions with Other Medicaments

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

The hepatotoxicity of Paracetamol, particularly after overdose, may be increased by drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants, and alcohol.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

Antivirals: Regular use of Paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia).

The use of drugs that induce hepatic microsomal enzymes such as anticonvulsants and oral contraceptives may increase the extent of metabolism of paracetamol resulting in reduced plasma concentrations of the drug and a faster elimination rate.

Statement on Usage During Pregnancy and Lactation

This product is intended to be used in children

Adverse Effects / Undesirable Effects

Adverse effects of paracetamol are rare and usually mild, although haematological reactions have been reported.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.

Overdose and Treatment

Symptoms:

Toxic symptoms include vomiting, abdominal pain, hypotension and sweating. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal hepatic necrosis. Clinical and laboratory evidence of hepatotoxicity may be delayed for up to one week. Major manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.

Treatment:

In cases of overdose, methods of reducing the absorption of ingested drug are important. Gastric lavage is essential even if several hours have elapsed. Prompt administration of 50g activated charcoal and 500ml iced mannitol 20% by mouth, may reduce absorption. If the history suggests that 15g Paracetamol or more has been ingested, administer one of the following antidotes:

Acetylcysteine 20% i.v.: Administer intravenously, 20% acetylcysteine (Parvolex, Glaxo) immediately without waiting for positive urine test or plasma level results: initial dose of 150mg/kg over 15 minutes, followed by continuous infusion of 50mg/kg in 500ml 5% glucose/dextrose over 4 hours and 100mg/kg in 1L 5% glucose/dextrose over 16 hours; or

OR

Oral Methionine: 2.5g immediately followed by three further doses of 2.5g at four hourly intervals. For a 3 year old child, 1g methionine every four hours for four doses has been used;

OR

Oral Acetylcysteine 5%: 140mg/kg as a loading dose, then 70mg/kg every 4 hours for a total of 17 maintenance doses. If more than ten hours have elapsed since the overdose was taken, the antidote may be ineffective

Storage Conditions

Store below 30°C

Protect from light

Keep container tightly closed.

Dosage Forms and Packaging Available

60ml, 90ml, 100ml and 120ml HDPE Bottle

90ml PET Bottle

Product Registration Holder & Manufacturer

Noripharma Sdn. Bhd.

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