

Lotemp Suspension 250 mg/5 mL

Name and Strength of Active Substance (s)

Each 5 ml contains:

Paracetamol.....250 mg

Preservatives:

Methylparaben.....0.2%w/v

Propylparaben.....0.04%w/v

Product Description

Orange, viscous with orange flavor suspension.

Pharmacodynamics

Pharmacological actions:

Paracetamol is the active metabolic of phenacetin and has antipyretic and analgesic activities. In peripheral tissue, paracetamol is a weak COX-1 and COX-2 inhibitor. Paracetamol appears to an equivalent to aspirin as an analgesic and antipyretic agent. However, paracetamol lacks anti-inflammatory properties, does not affect uric acid levels and does not inhibit platelet function.

Pharmacokinetics

Absorption

Immediate-release paracetamol is absorbed rapidly, and peak plasma levels are reached in 30-60 minutes. Paracetamol is distributed throughout most body fluids and is slightly bound to plasma proteins.

Distribution

Paracetamol is distributed throughout most body fluids and is slightly bound to plasma proteins.

Metabolism

Approximately 90% of paracetamol usually undergoes hepatic conjugation with glucuronide (40% to 67%) and sulfate (20% to 46%) to form inactive metabolites that are excreted in the urine. A small amount (5% to 15%) of paracetamol is metabolized to N-acetyl-p-benzoquinoneimine (NAPQI), and the resulting complex is rendered harmless and excreted. After a large ingestion of paracetamol, these pathways become saturated, and glutathione stores become depleted. Therefore, NAPQI concentrations increase, which may cause hepatotoxicity.

Excretion

The elimination half-life of paracetamol is about 2 to 3 hours. Less than 5% of paracetamol is excreted unchanged.

Indication

LOTEMP SUSPENSION 250 mg/5 mL is used for the relief of fever, headache, symptoms of cold and flu, Toothache, discomfort of teething and fever after vaccination.

Recommended Dose

The recommended dose can be calculated as 15 mg per body weight in kg per dose every 4 to 6 hours as needed.

*** Do not take more than 4 times within 24 hours;**

Not recommended in children under 1 month.

The table below provided the dose of paracetamol suspension 250 mg/5 mL to be given, based on average weight-age grid of children.

Child's Weight (kg)	Dose (ml)
12 – 13 kg	3 mL
14 – 16 kg	4 mL
17 – 19 kg	5 mL
20 – 23 kg	6 mL
24 – 26 kg	7 mL
27 – 29 kg	8 mL
30 - 33 kg	9 mL
34 – 39 kg	10 mL
40 – 42 kg	12 mL

Mode of Administration

Oral

Contraindication

When used for self-medication, do not use with other drug products containing paracetamol or if allergic to paracetamol or any of the inactive ingredients.

Warning and Precautions

This preparation contains PARACETAMOL.

Do not take any other paracetamol containing medicines at the same time.

- **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.

Ethanol use: Use with caution in patients with alcoholic liver disease; consuming 2 or more alcoholic drinks/day may increase the risk of liver damage.

Hepatotoxicity: Paracetamol has been associated with acute liver failure, at times resulting in liver transplant and death. Hepatotoxicity is usually associated with excessive paracetamol intake and often involves more than one product that contains paracetamol.

Self-medication: When used for self-medication, patients should be instructed to contact health care provider if symptoms get worse or new symptoms appear, redness or swelling is present in the painful area, fever lasts longer than 3 days (all ages), or pain lasts longer than 5 days for children and adolescent, if sore throat is severe, persists for longer than 2 days, or is followed by fever, rash, headache, nausea, or vomiting, consult health care provider immediately.

Glucose-6-phosphate dehydrogenase deficiency: Use with caution in patients with known glucose-6-phosphate dehydrogenase deficiency.

Hypersensitivity reactions: Hypersensitivity and anaphylactic reactions have been reported including life-threatening anaphylaxis; discontinue immediately if symptoms occur. Serious and potentially fatal skin reactions, including acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson

syndrome (SJS), and toxic epidermal necrolysis (TEN), have occurred rarely with paracetamol use. Discontinue therapy at the first appearance of skin rash.

Interactions with Other Medication

Alcohol (Ethyl)	Alcohol (Ethyl) may enhance the hepatotoxic effect of Paracetamol.
Barbiturates	Barbiturates may increase the metabolism of Paracetamol. This may 1) diminish the effect of paracetamol; and 2) increase the risk of liver damage. Exceptions; Amobarbital; Butabarbital; Butalbital; Methohexital; Pentobarbital; Secobarbital; Thiopental.
Busulfan	Paracetamol may increase the serum concentration of Busulfan.
Carbamazepine	Carbamazepine may increase the metabolism of Paracetamol. This may 1) diminish the effect of paracetamol; and 2) increase the risk of liver damage.
Cholestyramine Resin	Cholestyramine Resin may decrease the absorption of Paracetamol. Effect is minimal if cholestyramine is administered 1 hour after paracetamol.
Dapsone (Topical)	Dapsone (Topical) may enhance the adverse/toxic effect of Methemoglobinemia Associated Agents.
Dasatinib	Paracetamol may enhance the hepatotoxic effect of Dasatinib. Dasatinib may increase the serum concentration of Paracetamol.
Fosphenytoin-Phenytoin	Fosphenytoin-Phenytoin may decrease the serum concentration of Paracetamol. Specifically, serum concentrations of Paracetamol may be decreased (leading to decreased efficacy), but the formation of the toxic N-acetyl-p-benzoquinone imine (NAPQI) metabolite may be increased (leading to increased hepatotoxicity).
Imatinib	Paracetamol may enhance the hepatotoxic effect of Imatinib.
Isoniazid	Isoniazid may enhance the adverse/toxic effect of Paracetamol.
Lamotrigine	Paracetamol may decrease the serum concentration of Lamotrigine.
Metyrapone	Metyrapone may increase the serum concentration of Paracetamol. More importantly, by inhibiting the conjugative metabolism of paracetamol, metyrapone may shift the metabolism towards the oxidative route that produces a hepatotoxic metabolite.
Mipomersen	Paracetamol may enhance the hepatotoxic effect of Mipomersen.
Nitric Oxide	Nitric Oxide may enhance the adverse/toxic effect of Methemoglobinemia. Management: Monitor patients for signs of methemoglobinemia (e.g., hypoxia, cyanosis) when nitric oxide is used in combination with other agents associated with development of methemoglobinemia. Avoid lidocaine/prilocaine.
Phenylephrine (Systemic)	Paracetamol may increase the serum concentration of Phenylephrine (Systemic).
Prilocaine	Methemoglobinemia Associated Agents may enhance the adverse/toxic effect of Prilocaine. Combinations of these agents may increase the likelihood of significant methemoglobinemia. Management: Monitor patients for signs of methemoglobinemia (e.g., hypoxia, cyanosis) when nitric oxide is used in combination with other agents associated with development of methemoglobinemia. Avoid lidocaine/prilocaine.

Probenecid	Probenecid may increase the serum concentration of Paracetamol. Probenecid may also limit the formulation of at least one major non-toxic metabolite, possibly increasing the potential for formulation of the toxic NAPQI metabolite.
Sodium Nitrite	Methemoglobinemia Associated Agents may enhance the adverse/toxic effect of sodium Nitrite. Combinations of these agents may increase the likelihood of significant methemoglobinemia.
Sorafenib	Paracetamol may enhance the hepatotoxic effect of Sorafenib. Sorafenib may increase the serum concentration of Paracetamol.
Vitamin K Antagonists (eg, warfarin)	Paracetamol may enhance the anticoagulant effect of Vitamin K Antagonists. This appears most likely with daily paracetamol doses exceeding 1.3 or 2 g/day for multiple consecutive days.

Pregnancy and Lactation

Pregnancy: Paracetamol crosses the placenta and can be detected in cord blood, newborn serum, and urine immediately after delivery. Adverse events were observed in some animal reproduction studies. In human, epidemiologic data regarding oral paracetamol use in pregnant women have shown no increased risk of major congenital malformations in infants exposed in utero to the drug. However, prenatal constriction of the ductus arteriosus has been noted in case reports following maternal use during the third trimester, although this association was not confirmed in a large observational study. Additional adverse events such as wheezing and asthma in early childhood and adverse neurodevelopmental effects such as ADHD following in utero paracetamol exposure have been evaluated in multiple studies, but outcome information is conclusive. Paracetamol is considered appropriate for the treatment of pain and fever in pregnancy. It is recommended to be used at the lowest effective dose for the shortest duration of time.

Lactation: Paracetamol is distributed into human milk in small quantities after oral administration. Except for a single case report of a rash, adverse reactions have generally not been observed in breastfeeding infants. Paracetamol is considered compatible with breastfeeding when used in usual recommended doses.

Side Effects

Frequency not define:

Dermatologic – Acute generalized exanthematous pustulosis (intravenous); severe dermatological reaction (intravenous); skin/rash (oral/rectal); Stevens-Johnson syndrome (intravenous); toxic epidermal necrolysis (intravenous).

Endocrine & Metabolic – Decreased serum bicarbonate (oral/rectal) decreased serum calcium (oral/rectal) decrease serum sodium (oral/rectal) hyperammonemia (oral/rectal); hyperchloremia (oral/rectal); hyperuricemia (oral/rectal); increased serum glucose (oral/rectal).

Hematologic & Oncologic – Anemia (oral/rectal); leukopenia (oral/rectal); neutropenia (oral/rectal); pancytopenia (oral/rectal).

Hepatic – Increased serum alkaline phosphatase (oral/rectal); increased serum bilirubin (oral/rectal)

Hypersensitivity – Hypersensitivity reaction (rare) (oral/rectal)

Renal – Renal disease (analgesic) (oral/rectal).

Genitourinary – Nephrotoxicity (with chronic overdose) (oral/rectal).

Less than 1%, postmarketing, and/or case reports:

Hepatic – Hepatic injury (dose related).

Hypersensitivity – Anaphylaxis (intravenous); hypersensitivity reaction (intravenous)

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

Symptoms and Treatment of Overdose

Signs and Symptoms:

Symptoms and signs of paracetamol poisoning usually occur between 24 and 72 hours after consumption. Patients may present with nausea, vomiting, jaundice, abdominal pain, renal injury, coagulopathy.

Treatment:

In cases of overdose, methods of reducing the absorption of the ingested drugs are important. Despite the lack of significant early symptoms, patients should be referred to the 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. Gastric lavage is essential even if several hours have elapsed. Prompt administration of 50g activated charcoal and 500 ml iced mannitol 20% by mouth, may reduce absorption. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentration is unreliable). If the history suggests that 15g Paracetamol or more has been ingested, administer one of the following antidotes:

- 1) Acetylcysteine 20% I.V.: Administer intravenously, 20% acetylcysteine immediately without waiting for a 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.
- 2) 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.
- 3) 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 overdosage was taken, the antidote may be ineffective.

Effects on Ability to Drive and Use Machine

This medicine does not affect ability to drive and use machine.

Storage Condition

Store below 30°C. Protect from light.

Dosage Forms and Packaging Available

60 mL high density polyethylene bottle with polyethylene screw cap.

Name and Address of Manufacturer

Biolab Co., Ltd.

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