For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

CALPOL 500

WARNING: Taking more than daily dose may cause serious liver damage or allergic reactions (e.g. swelling of the face, mouth and throat, difficulty in breathing, itching or rash).

1. GENERIC NAME

Paracetamol Oral Suspension IP 500 mg/5mL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Paracetamol IP 500 mg
In a flavoured syrup base …q.s.
Color: Sunset Yellow FCF

List of Excipients

Pharma Grade Sugar, Methyl Paraben, Propyl Paraben, Agar, Flavour Pineapple Fresh (11228), BTM Flavour 7020, Citric Acid Monohydrate, Sodium Citrate, Sorbitol Solution 70% Non-crystalline, Propylene Glycol, Sucralose, Sodium Saccharine, Xanthan Gum, Sodium Lauryl Sulphate, Colour Sunset Yellow FCF, Purified Water.

3. DOSAGE FORM AND STRENGTH

Oral Suspension
An orange-coloured viscous suspension.

500 mg per 5 mL

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

CALPOL 500 is indicated for the treatment of mild to moderate pain and treatment of fever in adults and adolescents over 16 years of age.

4.2 Posology and Method of Administration

Mode of administration

For oral administration only

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Population	Dosing	Minimum dosing interval
Adult and adolescents over 16 years	500 mg (5 ml) up to three to four times a day, as required.	6 hours

Special populations

Renal Impairment

It is recommended, when giving paracetamol to patients with renal impairment, to reduce the dose and to increase the minimum interval between each administration to at least 6 hours unless directed otherwise by a physician. See table below:

Adults:

Glomerular Filtration Rate	Dose
10-50 ml/ min	500 mg every 6 hours
< 10 ml/ min	500 mg every 8 hours

Hepatic Impairment

In patients with hepatic impairment or Gilbert's Syndrome, the dose should be reduced or the dosing interval prolonged. The daily dose should not exceed 2g/day unless directed by a physician.

Elderly

Experience has indicated that normal adult dosage is usually appropriate. However, in frail, immobile, elderly subjects or in elderly patients with renal or hepatic impairment, a reduction in the amount or frequency of dosing may be appropriate.

The maximum daily dose should not exceed 60mg/kg/day (up to a maximum of 2g per day) in the following situations, unless directed by a physician:

- Weight less than 50kg
- Chronic alcoholism
- Dehydration
- Chronic malnutrition.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the excipients listed in Section 2 above.
Patients with severe hepatic dysfunction.
Do not use this medicine in children and adolescents under 16 years of age.

4.4 Special Warnings and Precautions for Use

Paracetamol should be administered with caution under the following circumstances (see *Section 4.2* where relevant):

- Hepatic impairment
- Chronic alcoholism
- Renal impairment (GFR≤50ml/min)
- Gilbert's Syndrome (familial non-haemolytic jaundice)
- Concomitant treatment with medicinal products affecting hepatic function
- Glucose-6-phosphate dehydrogenase deficiency
- Haemolytic anaemia
- Glutathione deficiency
- Dehydration
- Chronic malnutrition
- Weight less than 50kg
- Elderly

In general, medicinal products containing paracetamol should be taken for only a few days without the advice of physician or dentist and not at high doses.

If high fever or signs of secondary infection occur or if symptoms persist for longer than 3 days, a physician should be consulted.

Prolonged or frequent use is discouraged. Patients should be advised not to take other paracetamol containing products concurrently. Taking multiple daily doses in one administration can severely damage the liver; in such case medical assistance should be sought immediately.

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. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Do not take with any other paracetamol-containing products.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed serious or irreversible liver damage.

Patients should be advised that paracetamol may cause severe skin reactions. If a skin reaction such as skin reddening, blisters, or rash occurs, they should stop use and seek medical assistance right away.

Do not exceed the recommended dose. Keep out of the sight and reach of children.

Excipient warnings:
This product contains the following excipients:

- Methyl paraben and Propyl paraben: These may cause allergic reactions (possibly delayed).
- Propylene Glycol: This medicine contains 227.25 mg propylene glycol per 5ml dose. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old.

While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case- by-case basis.

4.5 Drug Interactions

The hepatotoxicity of paracetamol, particularly after overdosage, 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, however, concurrent use need not be avoided.

Absorption is reduced by cholestyramine. Therefore, the cholestyramine should not be taken within one hour if maximal analgesia is required.

Chloramphenicol: Increased plasma concentration of Chloramphenicol.

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.

Antivirals: Regular use of paracetamol possible reduces metabolism of zidovudine.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors.

4.6 Use in Special Populations

Pregnancy

A large amount of data on pregnant women indicates neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Lactation

Paracetamol is excreted in breast milk, but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breast feeding.

4.7 Effects on Ability to Drive and Use Machines

None

4.8 Undesirable 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.

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.

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

High Anion Gap Metabolic Acidosis (HAGMA) may occur with an unknown frequency.

High anion gap metabolic acidosis: Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see *section 4.4*). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Paracetamol overdose can result in liver damage which may be fatal.

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.

Overdose of paracetamol can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration.

Liver damage is likely in patients who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite become irreversibly bound to liver tissue. Overdose may cause hepatic failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Some patients may be at increased risk of liver damage from paracetamol toxicity:

Risk factors

If the patient

a) Patients with liver disease
b) Elderly patients
c) Young children
d) Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St. John's Wort or other drugs that induce liver enzymes or
e) Regularly consumes ethanol in excess of recommended amounts. or
f) Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms
Symptoms of paracetamol overdosage generally appear within the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain or patients may be asymptomatic. 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. 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 (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. The effectiveness of the antidote declines sharply after this time. 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 a liver unit.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Paracetamol is an analgesic and antipyretic. Its mechanism of action includes inhibition of prostaglandin synthesis, primarily within the central nervous system.

5.2 Pharmacodynamic Properties

Pharmacodynamic Effects
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.

Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.3 Pharmacokinetic Properties

Oral absorption is rapid and almost complete, it may be decreased if paracetamol is taken following a high carbohydrate meal.

There is no significant protein binding with doses producing plasma concentrations below 60mcg (μg)/ml but may reach moderate levels with high or toxic doses.

Approximately 90 - 95% of a dose is metabolised in the liver, primarily by conjugation with glucuronic acid, sulphuric acid, and cysteine. An intermediate metabolite, which may accumulate in overdosage after primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic.

Half-life is 1 to 4 hours; does not change with renal failure but may be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly, and in the neonate; may be somewhat shortened in children.

Time to peak concentration, 0.5 - 2 hours; peak plasma concentrations, 5 - 20mcg (μg)/ml (with doses up to 650mg); time to peak effect, 1 - 3 hours; duration of action, 3 - 4 hours.

Elimination is by the renal route, as metabolites, primarily conjugates, 3% of a dose may be excreted unchanged.

Peak concentrations of 10 - 15mcg (μg)/ml have been measured in breast milk, 1 - 2 hours following maternal ingestion of a single 650mg dose. Half-life in breast milk is 1.35 - 3.5 hours.

6. NONCLINICAL PROPERTIES

6.1 Animal Toxicology or Pharmacology

Non-clinical safety data for paracetamol have not revealed findings that are of relevance to the recommended dosage and use of the product.

7. DESCRIPTION

Oral Suspension
An orange-coloured viscous suspension.

Each 5 ml contains:
Paracetamol IP 500 mg

List of Excipients

Pharma Grade Sugar, Methyl Paraben, Propyl Paraben, Agar, Flavour Pineapple Fresh (11228), BTM Flavour 7020, Citric Acid Monohydrate, Sodium Citrate, Sorbitol Solution 70% Non-crystalline, Propylene Glycol, Sucralose, Sodium Saccharine, Xanthan Gum, Sodium Lauryl Sulphate, Colour Sunset Yellow FCF, Purified Water.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

In the absence of compatibility studies this medicinal product must not be mixed with other medicinal products.

8.2 Shelf Life

24 months

8.3 Packaging Information

60 mL Amber coloured PET bottle with 24mm squeeze and turn child resistant closure with measuring cup.

CHILD -RESISTANT PACKAGING: Turn the cap while keeping the ridges on both the sides of the cap pressed.

8.4 Storage and Handling Instructions

Store in a well closed container at temperature not exceeding 30ºC. Protect from direct sunlight. Do not freeze.
Keep out of reach of children. Shake well before use.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contraindications of *CALPOL 500*. Patients (and/or patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

Naxpar Pharma Pvt. Ltd.
182, Village- Gurumajra, Kishanpura,
Tehsil- Baddi, Dist. - Solan (H.P.), 174 101 (India)

For further information please contact:
GlaxoSmithKline Pharmaceuticals Limited.
Registered Office
Dr. Annie Besant Road, Worli
Mumbai 400 030, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

16 June 2026

Version: CAL500/PI/IN/2026/01

Adapted from:
Naxpar Prescribing information approved with the Form CT-23 dated 28-Mar-2025