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

CALPOL

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 Tablets IP 500 mg/650 mg
Paracetamol Fast Release Tablets 500 mg
Paracetamol Paediatric Oral Suspension IP 100 mg/120 mg/250 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Tablets

CALPOL 500 (Paracetamol Tablets IP 500 mg)
Each uncoated tablet contains Paracetamol IP 500 mg.

CALPOL 650 (Paracetamol Tablets IP 650 mg)
Each uncoated tablet contains Paracetamol IP 650 mg.

List of Excipients
Starch Maize, Pregelatinized Starch, Methylparaben, Magnesium Stearate, Purified Water (evaporates during processing).

Tablets with Optizorb

CALPOL 650+ (Paracetamol Tablets IP 650 mg)
Each uncoated tablet contains Paracetamol IP 650 mg.

CALPOL 500+ (Paracetamol Fast Release Tablets 500 mg)
Each uncoated tablet contains Paracetamol IP 500 mg.

List of Excipients
Pregelatinized Starch, Calcium carbonate, Povidone, Crospovidone, Alginic acid, Colloidal silicon dioxide, Magnesium stearate, Purified Water (evaporates during processing).

Oral Suspension

CALPOL 120 (Paracetamol Paediatric Oral Suspension IP 120 mg)
Each 5 ml contains:
Paracetamol IP 120 mg in a flavoured syrup base.
Colour: Carmoisine

CALPOL 250 (Paracetamol Paediatric Oral Suspension IP 250 mg)
Each 5 ml contains:
Paracetamol IP 250 mg in a flavoured syrup base.
Colour: Carmoisine.

List of Excipients
Sucrose, Sorbitol Solution, Agar, Microcrystalline Cellulose, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Sodium Citrate, Citric Acid Monohydrate, Sodium Lauryl Sulphate, Strawberry Flavor, Carmoisine Supra, Purified Water.

Oral Drops (Suspension)

CALPOL PAEDIATRIC DROPS (Paracetamol Paediatric Oral Suspension IP 100 mg)
Each ml (approx. 20 drops) contains:
Paracetamol IP 100 mg.
Colour: Sunset Yellow FCF.

List of Excipients
Sucrose, Liquid Glucose, Xanthan Gum, Glycerin, Monoammonium Glycyrrhizinate, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Sodium Chloride, Sodium Citrate, Citric Acid Monohydrate, Sunset Yellow FCF, Peppermint flavor, Purified Water.

3. DOSAGE FORM AND STRENGTH

Tablets
Oral Suspension
Oral Drops (Suspension)

For further details see section *2. Qualitative and Quantitative Composition*

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

Paracetamol is indicated for the treatment of mild-to-moderate pain and treatment of fever.

4.2 Posology and Method of Administration

Do not exceed the stated dose.

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

Formulation	Population	Dosing	Maximum daily dose	Minimum dosing interval
Tablet 500 mg (including tablets with Optizorb)	Adults including elderly/adolescents 12 years and older	500 mg to 1000 mg every 4 to 6 hours, as required.	4000 mg	4 hours
	Children 6 to 11 years	Maximum of 60 mg/kg administered in divided doses of 10-15 mg/kg in a 24-hour period. Children 6-8 years: 250 mg, (½ tablet) Children 9 to 11 years: 500 mg, (1 tablet) Maximum duration of continued use without medical advice: 3 days.	60 mg/kg/day	4 hours
Tablet 650 mg (including tablets with Optizorb)	Adults including elderly/adolescents 12 years and older	650 mg every 4 to 6 hours, as required.	3900 mg	4 hours
Oral suspension (120 mg/5 mL, 250 mg/5 mL) Oral drops, suspension (100 mg/mL)	Children aged 1 month and above	Maximum of 60 mg/kg administered in divided doses of 10-15 mg/kg in a 24-hour period. Maximum duration of continued use without medical advice: 3 days	60 mg/kg/day	4 hours
	Infants 1 to 3 months (for treatment of fever)	Maximum of 60 mg/kg administered in divided doses of 10-15 mg/kg in a 24-hour period. If fever persists for >24 hours (4 doses) seek medical advice to exclude a serious infectious cause.	60 mg/kg/day	4 hours

Formulation	Population	Dosing	Maximum daily dose	Minimum dosing interval
	Infants 1 to 3 months (for post-vaccination fever)	A single dose of 10 - 15 mg/kg for symptomatic relief of fever following vaccination. If a second dose is required, leave at least 4 hours between doses. After a second dose, no further dose to be given, medical advice should be sought if fever persists.	30 mg/kg	4 hours

Populations

- Children

  - The safety and efficacy of paracetamol have not been established in children less than 6 years of age for 500 mg tablet.
  - The safety and efficacy of paracetamol have not been established in children less than 12 years of age for 650 mg tablet.

- Renal Impairment

  Patients who have been diagnosed with renal impairment (GFR <60 mL/min) must seek medical advice before taking this medication. The restrictions related to the use of paracetamol products in patients with renal impairment are primarily a consequence of the paracetamol content of the drug (see *4.4 Special Warnings and Precautions for Use*).

- Hepatic Impairment

  Patients who have been diagnosed with liver impairment must seek medical advice before taking this medication. The restrictions related to the use of paracetamol products in patients with hepatic impairment are primarily a consequence of the paracetamol content of the drug (see *4.4 Special Warnings and Precautions for Use*).

4.3 Contraindications

Prior hypersensitivity to paracetamol or any of the components of formulations of paracetamol.

4.4 Special Warnings and Precautions for Use

The concomitant use with other products containing paracetamol is not recommended as it may lead to an overdose.

Paracetamol overdose may cause hepatic failure which may require liver transplant or be fatal (see *4.9 Overdose*).

There is an increased risk of paracetamol-related hepatic damage if used by patients with underlying hepatic disease.

Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication. Cases of hepatic failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index are chronic heavy users of alcohol or have sepsis.

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 a 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).

Cases of Severe Cutaneous Adverse Reactions (SCARs) such as Steven-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), erythema multiforme (EM) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. As SCARs can be life-threatening or fatal, treatment with paracetamol must be discontinued immediately and appropriate treatment should be given.

Keep out of sight and reach of children.

Excipients

Paracetamol oral suspension 120 mg/5 mL - Contains Azorubine/carmoisine (E122) which may cause allergic-type reactions.

Paracetamol oral suspension 250 mg/5 mL & Paracetamol oral drops, suspension 100 mg/ mL - Contains Sunset yellow FCF (E110 or FD&C Yellow No 6) which may cause allergic-type reactions.

4.5 Drug Interactions

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

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.

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 (see *4.4 Special Warnings and Precautions for Use*).

4.6 Use in Special Populations

Fertility

There is no data on the effects of paracetamol on human fertility. Available data does not indicate any effects on male and female fertility in animal studies (*see 6. Nonclinical Properties*).

Pregnancy

As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

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

Unlikely to cause an effect on ability to drive and use machines.

4.8 Undesirable Effects

Clinical trial data

Adverse events from historical clinical trial data are both infrequent and from limited patient exposure.

Post Marketing Data

The following convention has been utilised for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).

Events reported from extensive post-marketing experience at therapeutic/labeled dose and considered attributable are tabulated below by MedDRA System Organ Class (SOC). As these reactions are reported voluntarily from a population of uncertain size, the frequency of these reactions is not known but likely to be very rare (<1/10,000).

MedDRA SOC	**Adverse Reaction**
Blood and lymphatic system disorders	Thrombocytopaenia Agranulocytosis
Immune System disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema.

MedDRA SOC	Adverse Reaction
Metabolism and nutrition disorders	High anion gap metabolic acidosis*
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Hepatic dysfunction
Skin and Subcutaneous tissue disorders	SCARs (Stevens Johnson Syndrome, Toxic Epidermal Necrolysis, Erythema Multiforme, Acute Generalized Exanthematous Pustulosis, and Fixed Drug Eruption (see *4.4 Special Warnings and Precautions for Use*)

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

4.9 Overdose

Symptoms and signs

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain.

Paracetamol overdose may be injurious to liver.

Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and have peaked after 4 to 6 days. Abnormalities of glucose metabolism and metabolic acidosis may occur.

Risk factors for liver injury:
If the patient

a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort 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.

In severe poisoning, hepatic failure may progress to encephalopathy, disseminated intravascular coagulation, haemorrhage, hypoglycaemia, and cerebral oedema, which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Additionally, paracetamol overdose may result in signs and symptoms of acute renal failure. The signs and symptoms may include an elevation in serum urea, creatinine, and potassium levels, increased blood pressure, confusion, nausea, and vomiting. However, renal damage may be secondary to hepatic damage or may be the sole or primary toxic manifestation within 24 to

72 hours of paracetamol overdose. 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.

Treatment

Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage.

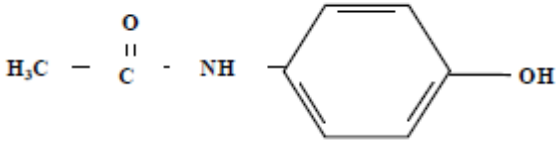
Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, 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.

If overdose is confirmed or suspected, seek immediate advice from your Poison Centre and refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver or renal damage.

Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

5. PHARMACOLOGICAL PROPERTIES

Anatomical Therapeutic Chemical (ATC) code: N02BE01
Pharmacotherapeutic group: Anilides



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 lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for patients with a history of disease or patients taking concomitant medication in whom peripheral prostaglandin inhibition would be

undesirable (such as, for example, those with a history of gastrointestinal bleeding or the elderly).

***In addition, the following apply to specific formulations*:**

***Tablets with Optizorb**:

In two dental pain studies conducted in patients following surgical removal of third molars, pain relief was observed at a median time of 15 minutes following administration of the 1000 mg dose of paracetamol tablets with Optizorb.

In clinical trials, paracetamol tablets with Optizorb demonstrated superiority with pain relief at 1000 mg dose compared to placebo and to paracetamol tablets with Optizorb at 500 mg dose. Paracetamol tablets with Optizorb at the 500 mg dose also demonstrated superiority with pain relief compared to placebo.

5.3 Pharmacokinetic Properties

Absorption

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.

Distribution

Binding to the plasma proteins is minimal at therapeutic concentrations.

Metabolism

Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates.

Elimination

Less than 5% is excreted as unmodified paracetamol.

***In addition the following apply to specific formulations*:**

Tablets:

Paracetamol is rapidly absorbed from the gastrointestinal tract and is distributed into most body tissues. Binding to plasma proteins is minimal at therapeutic concentrations. Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates; less than 5% is excreted as unmodified paracetamol. The mean plasma half-life is about 2.3 hours.

Tablets with Optizorb:

Paracetamol tablets with Optizorb contain a disintegrant system which optimises tablet dissolution compared to standard immediate release paracetamol tablets.

Human scintigraphy data demonstrate that paracetamol tablets with Optizorb generally start to disintegrate by 5 minutes post dose. Human pharmacokinetic data demonstrate that paracetamol can generally be detected in plasma by 10 minutes.

Human pharmacokinetic data demonstrate that early absorption of paracetamol (fraction of dose over the first 60 minutes) is 32% greater from paracetamol tablets with Optizorb compared to standard immediate release paracetamol tablets ($p<0.0001$). There is also less between-subject and less within-subject variability ($p<0.0001$) in early absorption of paracetamol from paracetamol tablets with Optizorb compared to standard immediate release paracetamol tablets.

Human pharmacokinetic data demonstrate that maximum plasma concentration of paracetamol is reached at least 25% faster for paracetamol tablets with Optizorb compared to standard immediate release paracetamol tablets in fasted and fed states ($p<0.01$).

Total extent of absorption of paracetamol from paracetamol tablets with Optizorb is equivalent to that from standard immediate release paracetamol tablets.

5.4 Clinical Studies

Mild-to-moderate pain

A double blind, single-dose parallel study in 120 patients with upper respiratory tract infection with acute sore throat and objective evidence of tonsillopharyngitis demonstrated statistically and clinically significant efficacy of a single 1000 mg dose of paracetamol tablet in reducing pain intensity and providing pain relief in sore throat over at hourly intervals 6 hour period, compared with placebo. This study used validated measures and differences were clinically relevant.

Three large, randomised, double-blind studies assessing the efficacy of paracetamol in tension headache have been reported, comparing several doses of paracetamol with other analgesics and placebo. Two studies demonstrated statistically significant superior cumulative pain relief values and cumulative sums of pain intensity differences over 6 hours for paracetamol 1000 mg compared with placebo. Significant differences compared with placebo were observed from one hour after dosing, although separation of benefit commenced as early as 30 minutes after dosing. The third study demonstrated that paracetamol 1000 mg gave statistically significant superior pain relief compared to placebo.

A randomised, double-blind, placebo-controlled study investigated the effect of treatments including paracetamol (1000 mg) in combination with pseudoephedrine in patients with the common cold. General muscular ache was assessed during the study and a significant superiority over placebo ($p<0.05$) was demonstrated for the paracetamol combination.

A large parallel group study assessed the efficacy of paracetamol 1000 mg compared with placebo in a single migraine attack. The paracetamol was significantly superior to placebo at 2 hours post-dose for headache response rate, pain-free rate and for other migraine headache symptoms such as photophobia, phonophobia and functional disability.

A large cross-over study assessed the efficacy of paracetamol 1000 mg compared with dihydroergotamine, paracetamol/dihydroergotamine combination and placebo in four

consecutive migraine attacks. All active treatments were significantly superior to placebo in reducing intensity of pain at 1 and 2 hours and brought a significantly faster abatement of pain.

A second crossover study compared paracetamol 900 mg with ibuprofen 400 mg in the treatment of classical migraine. Both treatments significantly reduced severity of pain compared with baseline.

Two placebo-controlled studies examined paracetamol efficacy in dysmenorrhoea. The first study was part of a pooled analysis which compared paracetamol 1000 mg with naproxen sodium 220 mg and placebo. The design was a randomised, double-blind, single dose, cross-over study in patients with primary dysmenorrhoea of moderate to severe intensity. For paracetamol, maximal pain relief was observed at 2 hours post-dose. Paracetamol showed significant pain relief at 2, 3 and 4 hours after administration versus placebo ($p<0.01$) and numerically superior pain relief at 5, 6 and 7 hours after administration. The second study demonstrated that paracetamol 650 mg was superior to placebo in reducing menstrual pain.

Six studies in dental pain are reviewed. All were large studies, randomised, group comparative and double-blind in design. All except one were placebo controlled. The non-placebo controlled study compared two doses of paracetamol with codeine 60 mg. One study was performed in pre-operative pain, all others were post-operative assessments. In all studies paracetamol 1000 mg was shown to be statistically superior to placebo or to codeine 60 mg.

A meta-analysis has of the efficacy of paracetamol in the treatment of osteoarthritis showed that paracetamol was significantly more effective in relieving pain due to osteoarthritis than placebo.

A study has been performed in acute and chronic moderately severe musculoskeletal pain (including ligament/bone pain, low back strain, osteoarthritis and 14 other conditions) in 90 patients. Pain was significantly reduced compared with baseline in the paracetamol group, but comparisons with placebo were not performed.

A large, well-designed study in adults with upper respiratory tract infection assessed the efficacy of 500 mg and 1000 mg doses of paracetamol compared with aspirin (500 mg or 1000 mg) or placebo for 6 hours after treatment. Compared to placebo, significant reductions were seen in the mean intensity of headache, aching and feverish discomfort ($p<0.001$) at 2, 4 and 6 hours after paracetamol 1000 mg. Compared to placebo, significant reductions were seen in the mean intensity of headache ($p<0.001$) at 2, 4 and 6 hours after paracetamol 500 mg. Further, with the 500 mg paracetamol dose, feverish discomfort ($p<0.001$ at 2 and 4 hours and $p<0.025$ at 6 hours) and achiness ($p<0.01$ at 1 and 4 hours) were significantly reduced as compared to placebo.

Two open-label, randomised comparative studies in children with upper respiratory tract infections reported significant ($p<0.05$) reductions in fever after the first dose of paracetamol.

In patients with an acute sore throat and at least one current symptom of upper respiratory tract infection, 1000 mg paracetamol showed significantly greater total pain relief over 30 minutes, 1 hour, and 6 hours compared with matching placebo.

In a small study (26 children, aged 18 month-13 years and 9 adults, aged 15-65 years) patients with acute otalgia were randomised to receive oral paracetamol or aural choline salicylate

dosed every 3-4 hours until pain relief was achieved. All patients receiving paracetamol (n=17) had reported pain relief within a time period of 10-90 minutes, 3 patients had mild pain, 9 patients had moderate pain and 5 had stronger pain.

A large, well-designed randomised controlled trial of 219 children (aged 1-6 years) with otitis media assessed the efficacy of 2 days' treatment with paracetamol (10 mg/kg three times daily, [n=73]), ibuprofen (10 mg/kg three times daily) or placebo. Tympanic score was reduced in all three groups at day 2; however there was no significant difference between the three treatment groups.

A Cochrane review reports that at 48 hours, children in the paracetamol group had less pain than those allocated to placebo. This data is based on the Cochrane authors' analysis of the results in the above-cited trial.

Fever

A large, well designed study in 392 adults with fever (associated with upper respiratory tract infection) assessed the efficacy of 500 mg (n=79) and 1000 mg (n=79) doses of paracetamol compared with placebo (n=78) for 6 hours after treatment. Both doses of paracetamol were effective compared to placebo ($p<0.001$) over the 4 hour period and significant temperature reduction for paracetamol persisted for a minimum of 6 hours. Another large, placebo-controlled study in 154 adults assessed a single 650 mg dose of paracetamol in an endotoxin-induced model of fever. This study showed a statistically significant and clinically relevant change from baseline in temperature over 8 hours for paracetamol (n=30) compared with placebo (n=30). Other controlled studies have demonstrated the antipyretic efficacy of paracetamol in children.

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

For further details see section *2. Qualitative and Quantitative Composition*

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

No data available.

8.2 Shelf Life

The expiry dates are indicated on the label and packaging.

8.3 Packaging Information

CALPOL 500 and CALPOL 650 and CALPOL 500+ and CALPOL 650+

CRSF (Child Resistant Senior Friendly) blisters in a carton.
or
High density polyethylene (HDPE) container with induction sealing (only for *CALPOL 500* and *CALPOL 500+*).

CALPOL 500 and *CALPOL 650* and *CALPOL 500+ and CALPOL 650+* come in special packaging (CRSF blisters in a carton) to prevent children removing them.

To take out a tablet gently push one end of the tablet through the foil layer.
For more information open the link below:
Child-Resistant Packaging Opening Instructions for Blister

CALPOL 120 and 250

Amber PET bottle with measuring cup.

CALPOL PAEDIATRIC DROPS

Amber glass bottle with a dropper with cover in a carton.

All pack presentations may not be marketed in the country.

8.4 Storage and Handling Instructions

CALPOL 500 and CALPOL 650 and CALPOL 500+ and CALPOL 650+

Store at temperature not exceeding 30°C. Protect from light and moisture.

CALPOL 120 and CALPOL 250

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.

CALPOL PAEDIATRIC DROPS

Store in a well closed container at temperature not exceeding 30ºC. Protect from direct sunlight.
Do not freeze.
Keep out of reach of children.
Unscrew the cover on the dropper. Pull out the teat and screw the dropper on to the bottle after removing the metal cap.
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*. Patients (and/or patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging.

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

11. DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

11-JUN-2025

Version: CAL/PI/IN/2025/02

Adapted from: Paracetamol NCDS Version 03 dated 12 May 2025