CALPOL PAEDIATRIC SUSPENSION

SCHEDULING STATUS:

S1 150 ml

S0 50 ml, 100 ml

1. NAME OF MEDICINE

CALPOL PAEDIATRIC SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Paracetamol	120 mg

Excipients with known effect

Methyl Hydroxybenzoate	0,1% m/v
Propyl Hydroxybenzoate	0,02% m/v

Contains sugar (Sorbitol 0,75 ml & Glucose 2,0 ml) per 5 ml

Alcohol Free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CALPOL is indicated for symptomatic relief of mild to moderate pain such as headache, sore throat, toothache, teething pains and fever associated with colds and flu.

4.2 Posology and method of administration

DO NOT EXCEED THE RECOMMENDED DOSE.

Shake the bottle before use.

Age	Average weight (kg)	Dose
3 – 6 months	6 -8	3,75 ml
6 – 24 months	8 – 12	5 ml
2 – 4 years	12 – 16	7,5 ml
4 – 6 years	16 - 20	10 ml

Infants under three months: NOT RECOMMENDED

May be given three to four times daily but with an interval of 4 hours between each dose. No more than four doses in any 24-hour period. Consult your doctor if no relief is obtained with the recommended dosage.

4.3 Contraindications

CALPOL is contra-indicated in patients with a previous history of hypersensitivity to paracetamol or excipients.

Severe hepatic impairment (Child Pugh C).

4.4 Special warnings and precautions for use

CALPOL contains paracetamol which may be fatal in overdose. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.

Underlying liver disease increases the risk of paracetamol-related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

Cases of hepatic dysfunction/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.

In patients with glutathione depleted states the use of paracetamol may increase the risk of metabolic acidosis.

If symptoms persist, medical advice must be sought.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Each 24 mg/ml (120 mg/5 ml) suspension contains sorbitol (E420) at 666.5 mg (2.0 ml) glucose (0.75 ml) per 5 ml and suspension.

Sodium methyl-, sodium ethyl- and sodium propyl- parahydroxybenzoates (E219, E215, E217) may cause allergic reactions (possibly delayed).

4.5 Interactions with other medicines and other forms of interactions

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.

4.6 Undesirable effects

DO NOT USE CONTINUOUSLY FOR LONGER THAN THREE DAYS WITHOUT CONSULTING YOUR DOCTOR.

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).

Body system	Undesirable effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia	Very rare
Immune system disorders	Anaphylaxis, cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, Steven-Johnson syndrome and Toxic Epidermal Necrolysis	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

Patients with the rare hereditary condition of sorbitol and maltilol due to fructose intolerance should not take **CALPOL Paediatric Suspension.**

4.7 Overdose

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately or take the person directly to a hospital. A delay in starting treatment may mean that the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5-10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment

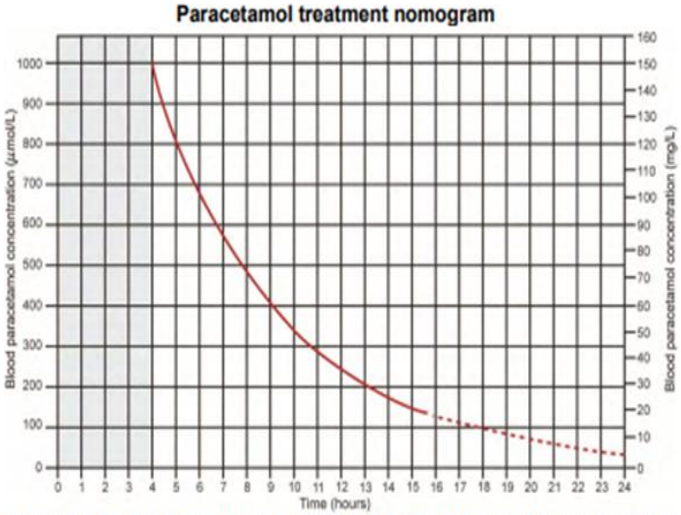
Although evidence is limited, it is recommended that any adult person who has ingested 5-10 g or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperous or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given **intravenously** over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next four hours and then 100 mg/kg in 1 000 ml dextrose injection over the next sixteen hours.

The volume of intravenous fluid should be modified for children.

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.



Source: Daly FF, Fountain JS, Murray L, Graudins A, Buckley NA; Panel of Australian and New Zealand clinical toxicologists. Guidelines for the management of paracetamol poisoning in Australia and New Zealand -explanation and elaboration. A consensus statement from clinical toxicologists consulting to the Australasian poisons information centres. Med J Aust. 2008 Mar 3;188(5):296-301.

LoE:III[xiv]

Nomogram extracted from Essential Medicines Guideline, South African Department of Health, 2015.

Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the “high risk treatment line”. Prothrombin index correlates best with survival. Monitor all patients with significant ingestions for at least 96 hours.

5. PHARMACOLOGICAL PROPERTIES

A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics.

5.1 Pharmacodynamics properties

Paracetamol has analgesic and antipyretic actions.

5.2 Pre-clinical safety data

None available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Malic acid, azorubine (E122), xanthan gum, maltilol liquid, strawberry flavour, sorbitol, nipasept sodium [sodium methyl parahydroxybenzoate, sodium ethyl parahydroxybenzoate and sodium propyl parahydroxybenzoate], anhydrous citric acid and purified water.

6.2 Shelf life

24 months

6.3 Special precautions for storage

Protect from light.

Exposure to air should be minimal.

Store in a well closed container at or below 25 °C.

Keep out of reach of children.

6.4 Nature and contents of container

Pink coloured uniform suspension with a strawberry odour.

Amber glass bottle of 150 ml with a white, child resistant, tamper evident closure with a white outer cap, natural inner cap and a natural tamper evident band.

Amber PET bottle 150 ml.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION AND MANUFACTURER

Haleon South Africa (Pty) Ltd.

11 Hawkins Avenue

Epping Industria 1

Cape Town,

7460

8. REGISTRATION NUMBER

A B/2.7/767

9. DATE OF FIRST AUTHORISATION

Date on the registration certificate of the medicine: 14 April 1989

10. DATE OF REVISION OF THE TEXT

Date of the most recently revised package insert as approved by council: 18 December 2024

Additional countries registration details:

Country	Scheduling status (or Category of distribution)	Registration no.
Botswana	S4	B9317485
Namibia	NS0	11/2.7/0043
Zambia	GS	025/018
Zimbabwe	HR	83/2.1/1671

ATC Code: N02BE01 - Anilides