HALEON

CALPOL TABLETS PI

CALPOL TABLETS: PI

SCHEDULING STATUS:

S0 for packs containing 2, 6, 10, 12, 16 or 24 film-coated tablets

S1 for packs containing 48, 96 or 100 film-coated tablets

PROPRIETARY NAME and dosage form:

CALPOL TABLETS (film-coated tablet)

COMPOSITION:

Each film-coated tablet contains 500 mg paracetamol.

The other ingredients are: pregelatinized maize starch, calcium carbonate, alginic acid, crospovidone, povidone (K-25), magnesium stearate, colloidal anhydrous silica, Opadry (White YS-1-7003), Water Purified and carnauba wax.

Sugar Free.

CATEGORY AND CLASS:

A 2.7. Antipyretic or Antipyretic and anti-inflammatory analgesics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties

Paracetamol is an antipyretic and analgesic.

Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

Clinical Efficacy

The perception of analgesia occurred from a median time of 15 minutes post dosing in adult patients after surgical removal of third molars with a CALPOL TABLETS dose of 1

gram. The 1-gram dose demonstrated superior analgesia compared to the CALPOL TABLETS 500mg dose and placebo. Both CALPOL TABLETS doses provided analgesia superior to placebo.

Pharmacokinetic properties

CALPOL TABLETS contain disintegrant excipient(s) which accelerates/improves the rate of disintegration/dissolution and absorption 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 metabolites - less than 5 % is excreted as unmodified paracetamol. The mean plasma half-life is about 2,3 hours and Tmax is reached within 30 to 60 minutes.

Human scintigraphy data demonstrate that paracetamol tablets with the disintegrant excipient(s) 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 disintegrant excipient(s). There is also less between-subject and less within-subject variability in early absorption of paracetamol from paracetamol tablets with the disintegrant excipient(s).

Human pharmacokinetic data demonstrate that maximum plasma concentration of paracetamol is reached at least 25% faster for paracetamol tablets with the disintegrant excipient(s) in fasted and fed states.

Total extent of absorption of paracetamol from paracetamol tablets with the disintegrant excipient(s) is equivalent to that from immediate release paracetamol tablets.

INDICATIONS:

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

CONTRA-INDICATIONS:

Contraindicated in patients with a previous history of hypersensitivity to paracetamol or excipients.

Severe hepatic impairment (Child Pugh C).

WARNINGS AND SPECIAL PRECAUTIONS:

Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other medicines containing paracetamol may lead to an overdose. 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.

Do not use continuously for longer than 10 days without consulting your doctor.

Very rare cases of serious skin reactions have been reported.

CALPOL TABLETS contains paracetamol and may be fatal in overdose. In the event of overdosage or suspected overdosage and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Control Centre must be contacted immediately.

DO NOT EXCEED THE RECOMMENDED DAILY DOSE.

Dosages in excess of those recommended may cause severe liver damage.

Sodium methyl-, sodium ethyl- and sodium propylparahydroxybenzoates may cause allergic reactions (possibly delayed).

If symptoms persist, medical advice must be sought.

INTERACTIONS:

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol as contained in CALPOL TABLETS with increased risk of bleeding; occasional doses have no significant effect. The rate of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption of paracetamol may be reduced by cholestyramine.

HUMAN REPRODUCTION:

Pregnancy

Safety and efficacy in pregnancy and lactation have not been established.

Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero showed indeterminate results. If used in pregnancy it should be used in the lowest effective dose for the shortest possible duration. Paracetamol is excreted in breastmilk.

DOSAGE AND DIRECTIONS FOR USE:

Do not exceed the stated dose.

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

Oral administration only.

Should not be used with other paracetamol-containing medicines.

Not more than four doses in any 24-hour period. Maximum daily dose: 4000 mg

Minimum dosing interval: 4 hours.

Ages and dosages were aligned with the UK and Irish PIs for paracetamol with the disintegrant system.

Adults (including the elderly) and children aged 16 years and over:

One to two film-coated tablets every 4 to 6 hours as required.

Maximum daily dose: 4 000 mg (8 film-coated tablets).

Children, 10 to ≤15 years of age:

One film-coated tablet every four to six hours as required:

No more than four doses in any 24-hour period.

Maximum duration of continued use without medical advice: 3 days.

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

Children under 10 years:

Not recommended for children under 10 years of age.

SIDE EFFECTS:

Body System	Undesirable effect	Frequency
Blood and lymphatic system disorders	Agranulocytosis, thrombocytopenia, leucopenia, pancytopenia, neutropenia, anaemia.	Very rare
Immune System disorders	Anaphylaxis, cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, and Stevens-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
Renal and urinary disorders	Renal colic, renal failure and sterile pyuria	Very rare
Gastrointestinal disorders	Pancreatitis	Very rare
Skin and subcutaneous tissue disorders	Allergic dermatitis * *Hypersensitivity reactions including skin rash and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes	Very rare

	more serious and accompanied by fever and mucosal lesions.	

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
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 overdosage of paracetamol 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/increased INR. 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 dysrhythmias have been reported.

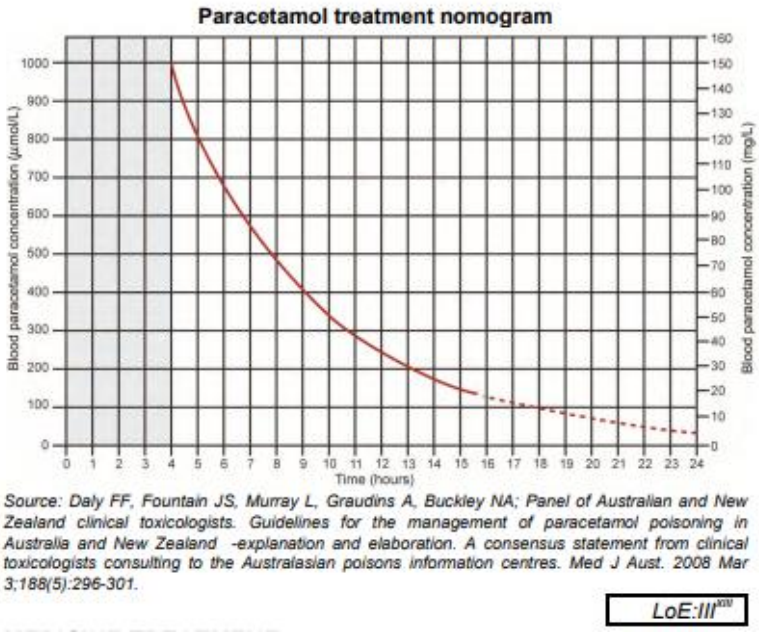
Treatment for Paracetamol Overdosage:

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, unless high, 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. Nomogram should be used only in relation to a single acute ingestion.



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.

Reporting of side effects

If you or your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

IDENTIFICATION:

White to off-white film-coated capsule-shaped tablet, circled “P” embossed one side, breakline on the other.

PRESENTATION:

The tablets are packed in polyvinylchloride/Aluminium foil blisters, or child resistant polyvinylchloride/Aluminium foil/PET blisters or paperpoly/polyethylene of 2 count. The blister packs are further packed into cardboard cartons or wallet style packs and sold in multiples of 12 count e.g. 12’s, 24’s etc.

STORAGE INSTRUCTIONS:

Store at or below 30 °C, in a dry place.
Keep blisters in the carton until required for use.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

44/2.7/0321

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Haleon South Africa (Pty) Limited
11 Hawkins Avenue
Epping Industria 1
Cape Town
7450

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

Date on the registration certificate of the medicine: 23 November 2017
Date of the most recently revised professional information as approved by council:
11 April 2025.

Additional country registration details:

Country	Scheduling status (or Category of distribution)	Pack size	Registration no.
Namibia	NS0	6, 10, 12, 16, 24	11/2.8/0008
	NS1	48, 96, 100	11/2.8/0008
Botswana	S4	12	BOT2404159
	S4	24	BOT2404159A
	S4	24	BOT2404159B

Name and address of manufacturer:

Haleon Dungarvan Limited
Knockbrack,
Dungarvan
Ireland