

CALPOL TABLETS

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

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

CALPOL TABLETS

Each film coated tablet contains 500 mg paracetamol.

Read all of this leaflet carefully because it contains important information for you.

CALPOL TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CALPOL TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CALPOL TABLETS with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet:

1. What CALPOL TABLETS is and what it is used for.
2. What you need to know before you use CALPOL TABLETS.
3. How to use CALPOL TABLETS.
4. Possible side effects.
5. How to store CALPOL TABLETS.
6. Contents of the pack and other information.

1. What CALPOL TABLETS is and what it is used for.

Each film-coated tablet contains 500 mg paracetamol.

The other ingredients are: 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. Preservative free.

CALPOL TABLETS is fast absorbed and 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.

2. What you need to know before you use CALPOL TABLETS.

What you need to know before you take CALPOL TABLETS:

- If you are allergic to paracetamol or any of the ingredients in the tablet.
- If you have severe liver problems.

Warnings and Precautions

Take special care with CALPOL TABLETS:

- **Do not exceed the recommended daily dose, as it may cause serious harm to your liver.**
- Do not use CALPOL TABLETS if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.
- Check with your doctor before use if you:
 - Have liver or kidney problems
 - Are underweight or malnourished
 - Regularly drink alcohol
 - Deep, rapid, difficult breathing
 - Feeling sick (nausea), being sick (vomiting)
 - Loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.

- Do not use continuously for more than 10 days without consulting your doctor or 3 days for your child.
- Very rare cases of serious skin reactions have been reported.
- Consult your doctor if no relief is obtained with the recommended dosage.

Other medicines with CALPOL TABLETS:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines). Consult your doctor before taking CALPOL TABLETS if you are using warfarin or similar medicines used to thin the blood, as this can increase the risk of bleeding. The rate of absorption of paracetamol may be increased by metoclopramide or domperidone and the absorption of paracetamol may be reduced by cholestyramine.

Pregnancy, Breastfeeding & Fertility:

If you are pregnant or breast feeding your baby while taking CALPOL TABLETS, please consult your doctor, pharmacist or other health care professional for advice. Paracetamol is excreted in breastmilk.

3. How to use CALPOL TABLETS.

Do not exceed the stated dose.

Do not take with any other product containing paracetamol.

Do not take more than 4 doses in any 24-hour period.

Do not take more frequently than every 4 hours.

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

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

Do not take more than 8 tablets per 24 hours.

Children, 10 to 15 years:

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

Do not give more than 4 doses in any 24-hour period.

Do not give more than 60 mg per kg body weight in 4 divided doses of 10-15 mg per kg body weight throughout the 24-hour period. Do not use for longer than 3 days without medical advice.

Children under 10 years:

Not recommended for children under 10 years of age.

If you take more CALPOL TABLETS than you should:

In the event of overdose, consult your doctor or pharmacist immediately. If neither is available, seek help without any further delay at the nearest hospital or poison control centre. You may be prone to paracetamol poisoning if you take repeated high doses (greater than 5 -10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, aids, malnutrition and if you use drugs such as barbiturates (for anxiety, insomnia and seizures), isoniazid (for tuberculosis), rifampicin (for tuberculosis), phenytoin (for seizures) and carbamazepine (for seizures).

Symptoms of paracetamol overdose seen in the first 24 hours and likely to remain for a week or more are:

- pale skin
- nausea
- vomiting
- loss of appetite
- abdominal pain

Other symptoms are:

- liver damage or injury 12 to 48 hours after taking CALPOL TABLETS.
- abnormalities of glucose breakdown.
- excess quantity of acid in the blood.
- liver damage which may progress to disease of the brain, coma and death.
- swelling on the brain.
- reduced contractions of the heart muscle may also occur.

You may also develop:

- acute kidney failure with acute death of kidney tubule cells even in the absence of severe liver damage.
- Changes in heart rate or rhythm.

If you have taken 5 - 10 grams or more of paracetamol (or if a child has had more than 140 mg/kg) within the preceding 4 hours, you or your child need immediate medical treatment. Contact your medical doctor or go to the nearest hospital or poison control centre without any further delay.

If you forget to take a dose of CALPOL TABLETS:

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects.

CALPOL TABLETS can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking CALPOL TABLETS, please consult your doctor, pharmacist or other health care professional for advice. If any of the following happen, stop taking CALPOL TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CALPOL TABLETS. You may need urgent medical attention or hospitalisation.

Stop taking this medicine and tell your doctor immediately if:

- you experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience a skin rash or peeling, or mouth ulcers.
- you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction with this product.
- you experience unexplained bruising or bleeding.

These reactions are rare.

Other side effects you may experience are:

- blood and bleeding disorders
- problems with your liver
- problems with your kidney
- inflammation of the pancreas

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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.

5. How to store CALPOL TABLETS.

Store at or below 30°C, in a dry place.

Keep blisters in the carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

Do not use after the expiry date as stated on the carton.

Return all unused medicine to your pharmacist for proper disposal.

Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information.

What CALPOL TABLETS contain:

Each film-coated tablet contains 500 mg paracetamol.

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

Sugar Free.

What CALPOL TABLETS looks like and contents of the pack

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

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.

HOLDER OF THE CERTIFICATE OF REGISTRATION

Haleon South Africa (Pty) Ltd
11 Hawkins Avenue
Epping Industria 1, 7450
Tel: (011) 745 6000

This leaflet was last revised on:

Date of the most recently revised professional information as approved by council: 11 April 2025.

Registration number:

44/2.7/0321

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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