

**GLAXOSMITHKLINE CONSUMER HEALTHCARE SOUTH AFRICA (PTY) LTD
CALPOL TABLETS REG. NO. 44/2.7/0321 (PARACETAMOL 500 mg)**

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0 for packs containing 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

Read 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 10 days.

COMPOSITION:

WHAT CALPOL TABLETS CONTAIN:

Each film-coated tablet contains 500 mg paracetamol.

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The other ingredients are: maize starch, calcium carbonate, alginic acid, crospovidone, povidone (K-25), magnesium stearate, colloidal anhydrous silica, titanium dioxide, hypromellose 3cP, hypromellose 6cP, macrogol, polysorbate 80, carnauba wax.

Sugar Free.

APPROVED INDICATIONS AND USE

WHAT CALPOL TABLETS IS USED FOR:

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.

INSTRUCTIONS BEFORE TAKING CALPOL TABLETS.

Do not take CALPOL TABLETS:

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

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:

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- Have liver or kidney problems
- Are underweight or malnourished
- Regularly drink alcohol

You may need to avoid using Calpol tablets altogether or limit the amount of paracetamol you take, as this may increase the risk of paracetamol-related liver damage.

- Check with your doctor before use if you have a severe infection, are severely malnourished, severely underweight or are a chronic heavy alcohol user as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:
 - 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.
- Consult your doctor if no relief is obtained with the recommended dosage.

Human Reproduction:

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.

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Taking 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.

INSTRUCTIONS ON HOW TO TAKE 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.

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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.
- abnormalities of glucose breakdown
- excess quantity of acid in the blood.

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- 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.

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 and tell your doctor immediately or go to the casualty department at your nearest hospital:

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- 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. 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

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

STORAGE AND DISPOSAL OF 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

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF CALPOL TABLETS:

The tablets are packed in polyvinylchloride/Aluminium foil blisters, or child resistant polyvinylchloride/Aluminium foil/PET blisters.

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.

IDENTIFICATION OF CALPOL TABLETS

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

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REGISTRATION NUMBER:

44/2.7/0321

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

GlaxoSmithKline Consumer Healthcare South Africa (Pty) Ltd

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7460

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

The date of registration of the medicine: 23 November 2017.

Date of the most recently revised patient information leaflet as approved by council: 06 November
2020