

PARALGIN[®] FORTE/PARALGIN[®] TABLETS

Paracetamol/Codeine (400mg/30mg, 500mg/8mg)

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What Paralgin[®] Forte/Paralgin[®] Tablets is used for

Paralgin[®] Forte/Paralgin[®] Tablets are indicated for the relief of painful disorder such as headache, menstrual pain, a condition involving muscle and bones pain, muscle pain, and nerve pain. It is also indicated as an analgesics and antipyretics in conditions accompanied by discomfort and fever such as common cold and viral infection. Paralgin[®] Forte/Paralgin[®] Tablets is an effective pain reliever after dental work and tooth extractions. Codeine is indicated in person older than 12 years of age for the treatment of acute moderate pain in which it is not consider to be relieved by other analgesics such as paracetamol or ibuprofen (alone).

How Paralgin[®] Forte/Paralgin[®] Tablets works

Paralgin[®] Forte/Paralgin[®] Tablets consists of two ingredients called Paracetamol and Codeine. Paracetamol appears to produce analgesic effect (pain relieve) and antipyretic effect (reduce fever) and it can be used on its own or with combination of other analgesics. Codeine belongs to a group of medicines called opioid analgesic of which act to relieve pain.

Before you use Paralgin[®] Forte/Paralgin[®] Tablets

- When you must not use it

Do not use Paralgin[®] Forte/Paralgin[®] Tablets if:

- You are allergic (hypersensitive) to paracetamol, codeine phosphate or to any of the other ingredients of this medicines.
- The person going to take the tablets is under 12 years of age. Paralgin[®] Forte/Paralgin[®] Tablets must not be given to children under 12 years of age because the risk of opioids toxicity due to the variable and unpredictable metabolism of codeine to morphine.
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- You are aged 12 years to 18 years with compromised respiratory function.
- You have severe and/or acute respiratory diseases.
- You have acute breathing difficulties such as bronchitis, unstable asthma, emphysema (serious lung disease), respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing).
- You have Glucose-6-phosphatedehydrogenase deficiency (an enzyme deficiency).
- You are an ultra-rapid metabolizer of CYP2D6.
- You have chronic constipation.
- You have liver failure.
- You are breastfeeding or planning to breastfeed.
- You have anxiety disorders.
- You have mental health problems.
- You have adrenal insufficiency (adrenal glands do not produce enough hormone).

Do not take codeine if you have a history of drug dependence, including alcohol dependence.

Do not take Paralgin[®] Forte/Paralgin[®] Tablets during the third trimester of pregnancy.

Do not take Paralgin[®] Forte/Paralgin[®] Tablets during labour, especially if the baby is premature.

This medicine may produce withdrawal effects in the newborn baby.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Paralgin[®] Forte/Paralgin[®] Tablets.

- Before you start to use it

Check with your doctor or pharmacist before taking Paralgin[®] Forte/Paralgin[®] Tablets if:

- You have severe kidney or liver problems.
- If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- Other medicines which contain paracetamol.
- Medicines used to help you relax, sleep or relieve anxiety, such as barbiturates, sedatives, tranquillisers.
- Hypnotics, gabapentinoids, cannabis and centrally-active anti-emetics.
- Benzodiazepines (medicines used as sedatives or to treat anxiety).
- Medicines containing alcohol (ethanol), e.g., some cough syrups.

- Medicines used to thin the blood such as warfarin.
- Medicine to treat epilepsy or fit.
- Metoclopramide or domperidone – used to stop you feeling sick (nausea) or being sick (vomiting).
- Propantheline, a drug used to relieve stomach cramps or spasms.
- Medicines for diarrhoea, such as kaolin, pectin, and loperamide.
- Medicines used to treat depression such as monoamine oxidase inhibitors.
- Other opioid analgesics used to treat pain.
- Quinidine, a medicine used to treat abnormal or irregular heartbeat. Phenothiazines and antipsychotic agents, medicines used to treat mental disorders.
- Chloramphenicol, an antibiotic used to treat ear and eye infections.
- Flucloxacillin, zidovudine or rifampicin, drugs used to treat infections.
- Chelating resin.
- Medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone).

Paralgin® Forte/Paralgin® Tablets with a benzodiazepine (medicine used as sedative or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

How to use Paralgin® Forte/Paralgin® Tablets

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Adult and children over 12 years

Two tablets to be taken with a glass of water, not more frequently than every 4 hours, do not exceed 8 tablets in any 24-hour period.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Toxic symptoms include vomiting, abdominal pain, hypotension, sweating, central stimulation with exhilaration and convulsion in children, drowsiness, respiratory depression, bluish or purplish discoloration of the skin due to low oxygen in body and coma.

While you are using Paralgin® Forte/Paralgin® Tablets

- Things you must do

- Tell all the doctors and pharmacists who are treating you that you are taking Paralgin® Forte/Paralgin® Tablets.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Paralgin® Forte/Paralgin® Tablets.
- If symptoms persist or get worse, consult a doctor because this could be a sign of a serious condition.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Paralgin® Forte/Paralgin® Tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Avoid taking Paralgin® Forte/Paralgin® Tablets with empty stomach.
- Serotonin syndrome: Paralgin® Forte/Paralgin® Tablets may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or fast heartbeat, seek medical attention immediately.
- Adrenal insufficiency: Long term use of Paralgin® Forte/Paralgin® Tablets may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.
- Infertility: Long term use of Paralgin® Forte/Paralgin® Tablets may cause reduced fertility. It is known whether these effects on fertility are reversible.

Driving and using machines

Paralgin® Forte/Paralgin® Tablets may cause drowsiness which may impair your ability to concentrate and react. If you are affected, do not drive or do not operate machines. Children should be supervised while bike riding or engaging in other potentially hazardous activities to avoid potential harm.

Side effects

Like all medicines, Paralgin® Forte/Paralgin® Tablets can cause side effects, although not everybody gets them.

This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Paracetamol: indigestion, sweating, skin rashes, swelling of the lower layer of skin, anaphylactic shock, difficulty breathing, drop in blood pressure, nausea, abnormal peripheral blood cell counts and severe skin reaction.

Codeine: nausea and vomiting, constipation, dizziness and drowsiness, skin rashes, swelling (inflammation) of the pancreas, confusional state, dysphoria (general sense of unease, dissatisfaction or unhappiness), euphoria (feeling of intense joy, excitement or happiness) seizure, headache, sleepiness, tiredness, hypotension, sedation, respiratory depression, dry mouth, itchiness, excessive constriction of pupil, ringing of noise in ear, urinary retention, ability to concentrate and react, swelling of the lower layer of skin and severe skin reaction.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Paralgin® Forte/Paralgin® Tablets

- **Storage**
Store in a dry place at below 30°C, protect from direct light and humidity
- **Disposal**
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- **What it looks like**
Paralgin® Tablets
Paracetamol 500mg, Codeine phosphate hemihydrate 8mg (White, round convex, 13mm diameter tablet inscribed with 'SL' logo on one side and the other plain)

Paralgin® Forte Tablets

Paracetamol 400mg, Codeine phosphate sesquihydrate 30mg (White, round convex, 12mm diameter tablet inscribed with 'SL' logo on one side and breakline on the other)

- **Ingredients**
 - Active ingredient(s)
Paracetamol
Codeine phosphate
 - Inactive ingredients
L-Hydroxypropyl-cellulose
Mannitol
Klucel EF
Microcrystalline cellulose
Syloid 244 FP EP
Stearic acid powder

- **MAL number(s):**
Paralgin® Forte Tablets
(MAL19920012ACZ)

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(MAL19920013ACZ)

Manufacturer

GoodScience Sdn. Bhd.
No.7, Jalan KPK 4/3,
Kawasan Perindustrian Kundang,
Kundang Jaya 48020 Rawang,
Selangor, Malaysia

Product Registration Holder

GoodScience Sdn. Bhd.
No.7, Jalan KPK 4/3,
Kawasan Perindustrian Kundang,
Kundang Jaya 48020 Rawang,
Selangor, Malaysia

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