

# PARALGIN<sup>®</sup> FORTE/PARALGIN<sup>®</sup> TABLET

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

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## What Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet is used for

Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet 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. 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 another analgesic such as paracetamol or ibuprofen (alone).

## How Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet works

Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> consists of two ingredients called Paracetamol and Codeine. Paracetamol appears to produce analgesic effect (pain relieve) and anti-pyretic 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<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet

### - When you must not take it

Do not use Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet, if you are/have

1. During pregnancy unless in the judgement of the physician the potential benefits outweigh the possible hazards to the fetus.
2. During lactation unless the expected benefits to the mother outweigh the potential risk to the neonate.
3. Post –operative pain management in children who underwent tonsil removal surgery.
4. Kidney and heart problems
5. History of heart failure or hypertension.

### -Before you start to take it:

Talk to your doctor before using Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet if the conditions below apply to you:

1. Bowel obstruction
2. Abdominal pain
3. Adrenal glands do not produce enough hormone
4. Central Nervous System depression
5. Head trauma
6. Liver/kidney impairment
7. Pregnancy
8. Breast-feeding

### -Taking other medicine:

Some medicines may interact with Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet when taken together. These include:

1. Metoclopramide and Domperidone
2. Warfarin
3. Central Nervous System Depressant known as tranquilizers such as monoamine oxidase inhibitors- MAOIs
4. Taking Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet with a benzodiazepine (medicine used as sedatives 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 take Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet

### -How much to take it

For adults, the usual starting dose is 1-2 tablets Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet every four to six hours in aday, taken with or after meals.

For children aged 12-18 years old dose of Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> 1 Tablet up to 4 times daily.

It is recommended not to exceed 8 tablets daily.

### Children

1. Children aged less than 12 Years Codeine should not be used in children below the age of 12 years because the risk of opioids toxicity due to the variable and unpredictable metabolism of codeine to morphine.
2. Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet is contraindicated in children below the age of 12 year for symptomatic treatment of cold.
3. Children aged 12 years to 18 years Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet is not recommended for use in children aged 12 year to 18 years with compromised respiratory function.

### -When to take it

Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet can be taken with or after meals.

### -How long to take it

Refer to your pharmacist or doctor for advice.

### -If you forget to take it

You need to take it immediately and do not take double dose to make up for a forgotten dose.

### -If you take too much (overdose)

1. Symptoms Contact your doctor immediately or go to Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there

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are no sign of discomfort or poisoning. You may need urgent medical attention.

Clinical features including diarrhea, loss of appetite, nausea or vomiting, stomach cramps, breathing difficulty, depression, bluish or purplish discoloration of the skin due to low oxygen in body.

## While you are using it

### -Things you must do

Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet may cause dizziness or drowsiness in some people. If affected do not drive car, operate machinery or do anything else that could be dangerous if you are dizzy or drowsy. Children should not ride bikes if affected and should be supervised to avoid potential harm.

### -Things you must not do

Do not take more than what your pharmacist or doctor prescribed.

### -Things to be careful of

1. Avoid taking Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet with empty stomach.

2. Serotonin syndrome: Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet 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 a fast heartbeat, seek medical attention immediately.

3. Adrenal insufficiency: Long term use of Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet 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.

4. Infertility: Long term use of Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet may cause reduced fertility. It is not known whether these effects on fertility are reversible.

## Side effects

1. 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.
2. Mild drowsiness. You may experience constipation and abnormal movement of muscular coordination within the gall bladder.
3. High doses of Paracetamol may increase the activity of coumarin anticoagulant.
4. Codeine phosphate potentiates the effect of alcohol and other central depressive drugs.
5. Other reactions include experiencing state of excitement, state of unease, abdominal pain and itchiness.

Please consult your doctor/pharmacist for further information.

You may report any side effects or adverse drug reactions directly to the Centre of Adverse Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) “[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]”

## Storage and disposal of Paralgin<sup>®</sup> Forte/Paralgin<sup>®</sup> Tablet

### -Storage

Store in a cool dry place at below 30°C, protect from direct light and humidity.

### -Disposal

Consult your doctor or pharmacist how to dispose the medicine of which no longer required or has expired.

## Product description

### -What it looks like

Paralgin<sup>®</sup>- Paracetamol 500mg, Codeine phosphate hemihydrate 8mg (White, round convex, 13 mm diameter tablet inscribed with SL on one side and plain on the other side).

Paralgin<sup>®</sup> Forte- Paracetamol 400mg, Codeine phosphate sesquihydrate 30mg (White, round convex, 12mm diameter tablet inscribed with SL on one side and breakline on the other).

### -Ingredients

-Active ingredient:  
Paracetamol  
Codeine Phosphate

-Inactive ingredients:  
L-Hydroxypropyl- cellulose  
Mannitol  
Klucel EF  
Microcrystalline Cellulose  
Syloid 244 FP EP  
Stearic acid powder

### -MAL Number

Paralgin<sup>®</sup> Forte Tablet -  
MAL19920012ACZ

Paralgin<sup>®</sup> Tablet -  
MAL19920013ACZ

## Manufacturer

GoodScience Sdn. Bhd. (182627-W)  
No. 7, Jalan KPK 4/3,  
Kawasan Perindustrian Kundang,  
Kundang Jaya, 48020 Rawang,  
Selangor Darul Ehsan, Malaysia.

## Product Registration Holder

GoodScience Sdn. Bhd. (182627-W)  
No. 7, Jalan KPK 4/3,  
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Kundang Jaya, 48020 Rawang,  
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29/09/2023

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