

PARADEINE TABLET

Paracetamol / Codeine Phosphate (500mg / 8mg)

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What Paradeine Tablet is used for

For the relief of mild to moderately severe pain.

How Paradeine Tablet works

Paracetamol and codeine phosphate are painkillers that work together in different ways to relieve pain.

Before you use Paradeine Tablet

- When you must not use it
- Hypersensitivity to Paracetamol or Codeine.
- In children below the age of 12 years for the symptomatic treatment of colds due to an increased risk of developing serious and life-threatening adverse reactions.
- In all paediatric patients (0-18 years of age) who undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to increased risk of developing serious and life-threatening adverse reactions.
- In women who are breastfeeding.
- In individuals for whom it is known they are CYP2D6 ultra-rapid metabolisers.

This preparation contains Paracetamol. Do not take other Paracetamol containing medicines at the same time.

Pregnancy and lactation

Do not take Paradeine Tablet if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Paradeine Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor if:

- You are patients with impaired kidney or liver function.
- You are taking other drugs which affect the liver.

- You have underactive thyroid, Addison's disease and enlargement of the prostate gland or constriction of the urethra.

- 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.

How to use Paradeine Tablet

- How much to use

Adults: 1-2 tablets 3-4 times a day.

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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Paradeine Tablet for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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 think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much Codeine Phosphate may cause respiratory depression, coma, abnormal constriction of pupils, bluish discoloration to the hands or feet, weak pulse, low blood pressure, spasm of gastrointestinal tract and biliary tracts. Death from respiratory failure may occur.

Taking too much Paracetamol may cause vomiting, loss appetite, nausea,

epigastric pain. Liver damage, yellowish to the skin may follow soon.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Paradeine Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take other Paracetamol containing medicines at the same time.

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

Do not take any new medicines without consulting your doctor.

Do not give Paradeine Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Not recommended for children under 12 years of age.

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.

Do not take more than the recommended dosage or the physician's advice. Codeine may cause drowsiness and it may be habit forming.

Side effects

Like all medicines, Paradeine Tablet can cause side effects, although not everybody gets them.

Common side effects are dizziness, nausea and vomiting, gastrointestinal discomfort, lightheadedness, sedation, shortness of breath, allergic reactions, extreme happiness, constipation, itchiness and breathing disorder.

Cutaneous hypersensitivity reactions including skin rashes, swelling under the skin, Steven Johnsons Syndrome/Toxic Epidermal Necrolysis have been reported.

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Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website nptra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Paradeine Tablet

- Storage

Keep out of reach of children
Store in dry place below 30°C
Protect from light

- 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

White in colour, flat, round and scored with 'P' marking; uncoated tablet.

- Ingredients

- Active ingredients

Paracetamol & Codeine Phosphate

- Inactive ingredients

Corn Starch, Lactose Powder 200 Mesh, PVP K90, Magnesium Stearate

- MAL number:

MAL19913256AZ

Manufacturer & Product Registration Holder

Dynapharm (M) Sdn. Bhd.
2497, Mk 1 , Lorong Perusahaan Baru 5 ,
Kawasan Perusahaan Perai 3, 13600
Perai , Pulau Pinang , Malaysia.

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