

DICODONE TABLET

Paracetamol/Codeine Phosphate (500mg/8mg)

What is in this leaflet

1. What Dicodone is used for
2. How Dicodone works
3. Before you take Dicodone
4. How to take Dicodone
5. While you are taking it
6. Side effects
7. Storage and Disposal of Dicodone
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Dicodone is used for

Dicodone is used to relieve pain such as headache, stomach pain, conditions involving musculoskeletal pain and to relieve discomfort and fever in cold and viral infections. It is also used to manage pain associated with dental procedure.

Dicodone is indicated in individuals above 12 years old who haven't found relief with other painkillers.

How Dicodone works

Dicodone contains two active ingredients which are paracetamol and codeine phosphate.

Paracetamol and codeine phosphate work together to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to reduce fever.

Before you take Dicodone

-When you must not take it

Do not take this medicine if:

- you are allergic to paracetamol, codeine or any other ingredients of this medicine (listed in Product Description)
- below 12 years old
- below 18 years old that has undergone certain sleep apnea surgeries (tonsils or adenoids removal)
- you know you metabolize codeine very quickly into morphine (CYP2D6 ultra-rapid metabolizers)

Pregnancy and lactation

If you are pregnant, planning to get pregnant or think you may be pregnant, discuss with your doctor before starting any medicine.

Take Dicodone with caution if taken while pregnant, especially in the third

trimester. Take of Dicodone should be avoided during the third trimester of pregnancy and during labor, as it may cause harm to the baby.

Dicodone is secreted into breast milk and may affect your baby. Therefore, do not take Dicodone while breastfeeding.

-Before you start take it

Tell your doctor if you have or have ever had any other health problems / medical conditions, including:

- liver disease
- kidney disease
- any breathing problems

-Taking other medicines

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

Tell your doctor if you are using, including any of the following medicines:

- metoclopramide or domperidone (commonly used for nausea, vomiting)
- cholestyramine (medication used to lower high levels of cholesterol in the blood)
- anticoagulant medications such as warfarin
- benzodiazepines (sedative medication commonly used to treat anxiety and insomnia)
- serotonergic (medications commonly prescribed for various psychiatric conditions,
- other morphine or opioid-containing medications
- other paracetamol-containing medications

How to take Dicodone

Follow all directions given to you by your doctor and pharmacist carefully.

-How much to take

Adults and children over 12 years old :

Take 2 tablets by mouth every 4 hours as needed, maximum up to 8 tablets daily. Do not crush, break, chew or dissolve the tablets - swallow whole.

Note: Children aged 12 years to 18 years: Your doctor will decide whether you can take Dicodone based on your respiratory conditions.

-When to take it

Swallow tablets whole with a glass of water, every 4 hours or as directed by your doctor.

-How long to take it

Take Dicodone for the duration as your doctor recommends.

Discontinue if pain persists or worsens while taking Dicodone and see doctor as soon as possible.

-If you forget to take 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 take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if 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 many tablets may lead to paracetamol toxicity and cause liver problems, bleeding disorders, low blood sugar, kidney problems, coma and death if not treated promptly. Also, symptoms of codeine overdose include severe drowsiness, confusion, small pupils, slow/shallow breathing, nausea.

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 Dicodone.

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

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Take Dicodone only with a doctor's prescription.

- Nausea
- Vomiting

Magnesium stearate
Povidone 30

-Things you must not do

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

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

-Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel dizzy or drowsy, do not drive or use machines and contact your doctor immediately.

Stop using Dicodone if severe skin reactions such as reddening, blisters, or rash occur and seek immediate medical assistance. These could be signs of a serious condition.

Do not drink alcohol while taking Dicodone.

Be aware of any breathing problems that may occur while taking Dicodone.

Dicodone may lead to adrenal insufficiency, especially after prolonged use. Symptoms include nausea, vomiting, weakness, and low blood pressure. Your doctor might need to do some laboratory test to diagnose and treat if needed.

Cases of serotonin syndrome have been reported. Tell your doctor about any mental health changes (for example agitation, anxiety, restlessness, any abnormal movement).

Consult doctor if you notice significant decrease in sex drive.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Side effects of codeine:

- Lightheadedness
- Dizziness
- severe drowsiness or sleepiness

Side effects of paracetamol:

- Generally well-tolerated when taken in recommended doses.
- Rare side effects include skin reactions, such as hives, swelling and rash
- More serious skin reactions such as Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis.

Postmarketing Experience:

- Serotonin Syndrome (See -Things to be careful of)
- Adrenal Insufficiency (See -Things to be careful of)
- Chronic use may cause symptoms like low sex drive,, impotence, or infertility.

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 Dicodone

-Storage

Store 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 to off white, round, biconvex tablet with a breakline on one side and plain on the other.

Ingredients

- Active ingredients:
Each tablet contains:
Paracetamol 500mg
Codeine Phosphate 8mg

- Inactive ingredients:
Potassium sorbate
Talcum
Corn starch

-MAL number:

MAL19871077AZ

Manufacturer

Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai.
51/2 Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
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