

PARANOR 500mg Tablet

Paracetamol 500mg

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What PARANOR 500mg used for

PARANOR 500mg Tablet is used for the relief of fever.

For the relief from mild to moderate including: headache, migraine, backache, musculoskeletal pain, myalgia and neuralgia, dysmenorrhea, pain of osteoarthritis, toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from colds, influenza and sore throats.

How PARANOR 500mg works

PARANOR 500mg Tablet has analgesic (pain relief) and antipyretic (anti-fever) properties.

Before you use PARANOR 500mg

-When you must not use it

Do not take PARANOR 500mg Tablet if you are allergic to Paracetamol or Acetaminophen and other ingredients. If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

- Before you start to use it

This product contains Paracetamol. Do not take other Paracetamol containing medicine at the same time. Your doctor needs to know before you take PARANOR 500mg Tablet

- if you have kidney or liver problem. PARANOR 500mg Tablet should

also be taken with care when you take other medicines that affect the liver.

Discuss with your doctor or pharmacist first if you are pregnant or breastfeeding. Problems in human have not been reported when taking PARANOR 500mg Tablet during pregnancy or breastfeeding.

-Taking other medicines

Tell your doctor or pharmacist before taking PARANOR 500mg Tablet, if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

The effects of some medicines may be affected if other medicines are used at the same time.

Inform your doctor if you are using PARANOR 500mg Tablet in combination with the alcohol, liver enzyme inducers and hepatotoxic medications. Risk of liver toxicity increased with liver enzyme inducers and medicines that are known to be toxic to the liver

How to use PARANOR 500mg

Always take the medicine exactly as your doctor or pharmacist has told you. Read the direction on the labels carefully.

- How much to use

- Adults and children aged 12 years and over: 500mg to 1g paracetamol, taken every 4-6 hours as required up to a maximum of 4 g daily.
- Children 6 to 11 years: 250mg - 500mg every 4 to 6 hours as required.

Maximum daily dose: 60mg/kg presented in divided doses of 10-15mg/kg throughout 24 hour period dose

- When to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

- How long to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

If you forget to use

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

If you use to much (overdose)

Symptoms:

Toxic symptoms include vomiting, abdominal pain, hypotension and sweating. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal hepatic necrosis. Clinical and laboratory evidence of hepatotoxicity may be delayed for up to one week. Major manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.

Treatment:

In cases of overdose, methods of reducing the absorption of ingested drug are important. Gastric lavage is essential even if several hours have elapsed. Prompt administration of 50g activated charcoal and 500ml iced mannitol 20% by mouth, may reduce absorption. If the history suggests that 15g

Paracetamol or more has been ingested, administer one of the following antidotes:

Acetylcysteine 20% i.v.: Administer intravenously, 20% acetylcysteine immediately without waiting for positive urine test or plasma level results: initial dose of 150mg/kg over 15 minutes, followed by continuous

PARANOR 500mg Tablet

Paracetamol 500mg

infusion of 50mg/kg in 500ml 5% glucose/dextrose over 4 hours and 100mg/kg in 1L 5% glucose/dextrose over 16 hours; or

OR

Oral Methionine: 2.5g immediately followed by three further doses of 2.5g at four hourly intervals. For a 3 year old child, 1g methionine every four hours for four doses has been used;

OR

Oral Acetylcysteine 5%: 140mg/kg as a loading dose, then 70mg/kg every 4 hours for a total of 17 maintenance doses. If more than ten hours have elapsed since the overdose was taken, the antidote may be ineffective

While you are using it.

-Things you must do

Take the medication exactly as your doctor prescribed.

- Tell all the doctors, dentists and pharmacists treating you that you are taking PARANOR 500mg Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not give PARANOR 500mg Tablet to anyone else, even if their symptoms seem similar to yours. Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

-Things to be careful of

Avoid drinking alcohol while taking this medication.

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 serious condition. If these reactions occur, stop use and seek medical assistance right away.

Side effects

All medicines may have some unwanted side effects. Unwanted side effects do not always occur in every person. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PARANOR 500mg Tablet.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

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 PARANOR 500mg Tablet.

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

A white to off white round film coated tablet with score line one side and plain on the other side.

Active Ingredients:

Paracetamol
(as paracetamol DC Granules 90%)

Inactive ingredient

- Corn Starch
- Opadry QX white (contains
 - Macrogol (PEG) Polyvinyl Alcohol Graft Copolymer
 - Talc
 - Titanium Dioxide
 - Glycerol Monocaprylocaprate
 - Polyvinyl Alcohol
- Purified water

Ingredients consist in - Active Ingredient – Paracetamol (as Paracetamol DC Granule):

- Pregelatinized starch
- Povidone K30
- Stearic Acid
- Sodium Starch Glycolate
- Purified water

MAL number:

Manufacturer and Product Registration Holder:

Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Miles off Jalan Meru
41050 Klang, Selangor

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