

# NITRAPAM TABLET

Nitrazepam (5mg)

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## What Nitrapam Tablet is used for

Nitrazepam is the active ingredient of Nitrapam Tablets. It belongs to a group of medicines called benzodiazepine which is widely used as a sedative/hypnotic and in the management of myoclonic seizures (fits or convulsions with quick, involuntary muscle jerk).

## How Nitrapam Tablet works

Nitrazepam works by affecting the way certain brain chemicals (neurotransmitters) transmit messages. This has a calming effect which helps you to sleep.

## Before you use Nitrapam Tablet

- When you must not use it
  - If you have an eye problem called acute narrow angle glaucoma (increased pressure in the eye).
- Before you start to use it

You must tell your doctor if:

  - You have allergies to any medicine which you have taken previously to treat your current condition.
  - You have impaired liver function.
  - You are pregnant, trying to become pregnant or breast-feeding. It is found in breast milk, use with caution in nursing women.

## - Taking other medicines

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

Central nervous system (CNS) depressants, other such as alcohol, analgesics (pain killer), general anesthetics and tricyclic antidepressants: - concurrent use may increase the effect of benzodiazepines including Nitrapam.

Concurrent use of benzodiazepine with a narcotic analgesic, the dosage of narcotic should be reduced by at least one-third and administered in small increment.

## How to use Nitrapam Tablet

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

## - How much to use it

Adults: as hypnotic, the usual dose is 5mg to 10mg at night

Children: dosage up to 12 years not established.

## - When to use it

Use as directed by your doctor or pharmacist.

## - How long to use it

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

## - If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten 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.

## While you are using it

### - Things you must do

- If you do become pregnant whilst taking Nitrapam Tablet, tell your doctor.
- It should be used in caution if you have severe breathing (respiratory failure) or lungs problem (chronic obstructive lung disease).
- Inform your doctor immediately if anaphylaxis (severe allergic reactions) and angioedema (severe facial swelling) occurs as early as the first time the product was taken.
- Be caution of complex sleep-related behaviours which may include sleep driving, making phone calls, preparing and eating food (while asleep).

*Caution: this preparation may be habit forming on prolonged use.*

### - Things you must not do

Do not give Nitrapam Tablet to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Nitrapam Tablet for you and your condition.

Do not operate any vehicles or machinery as Nitrapam can cause drowsiness. These effects are enhanced by the simultaneous administration of depressants such as alcohol.

- ***Things to be careful of***  
Abrupt medicine withdrawal (symptoms that occur upon the abrupt discontinuation or decrease in intake of medications) may result in rebound insomnia (inability to sleep), an abstinence syndrome similar to barbiturate withdrawal seizures or rarely psychosis (a serious mental disorder characterized by defective or lost contact with reality often with hallucinations or delusions).

#### **Side effects**

Like all medicines, Nitrapam Tablet can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Drowsiness, light-headedness and ataxia (the loss of full control of bodily movements) are the most common and are often dose-dependent.
- Other effects occasionally observed include low blood pressure, some respiratory depression, nausea and constipation (difficult passage of stool), changes in salivation, blurred vision and diplopia (double vision), dysarthria (slurred or slow speech), skin rashes, urinary retention, incontinence (inability to hold the urine in the bladder), mental depression, tremor (an involuntary quivering movement), headache, confusion, slurred speech, vertigo (spinning sensation) and changes in libido (sexual desires).
- Rarely liver disease and blood dyscrasia (abnormal condition of the blood or bone marrow) occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers→Reporting)

#### **Storage and Disposal of Nitrapam Tablet**

- ***Storage***  
Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Store below 25°C in a well-closed container. Protect from light.

#### **Keep out of the reach and sight of children.**

- ***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***  
The tablets are a blue, round, flat of 11mm diameter tablet with 'MPI' marking.

They are supplied in 100 x 10's blisterpack.

- **Ingredients**
  - Active ingredient  
Each tablet contains 5mg of Nitrazepam.
  - Inactive ingredients  
The other ingredients are lactose, microcrystalline cellulose pH101, corn starch, potato starch, magnesium stearate and indigocarmine.

- ***MAL number***  
MAL19900511AZ

#### **Manufacturer and Product Registration Holder**

Malaysian Pharmaceutical Industries Sdn. Bhd.  
Plot 14, Lebuhraya Kampung Jawa,  
11900 Bayan Lepas, Penang, Malaysia.

#### **Date of Revision**

22/03/2016

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