

CONSUMER MEDICINE INFORMATION

NITRADOS™

Nitrazepam 5mg Tablets

- This leaflet answers some common questions about NITRADOS™ Tablets. It does not contain all the available information. It does not replace talking to your doctor or pharmacist.
- If you have any questions or concerns, talk to your doctor or pharmacist.

In this leaflet:

1. What is NITRADOS™ and what is it used for
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What is NITRADOS™ and what is it used for?

NITRADOS™ contains the active ingredient Nitrazepam. It belongs to a group of medicines known as benzodiazepines.

NITRADOS™ is used for short term treatment of sleeplessness. NITRADOS™ shortens the time to fall asleep and lengthens the duration of sleep.

Before you take NITRADOS™

Do not take NITRADOS™ Tablets if you:

- are allergic (hypersensitive) to nitrazepam or other benzodiazepines or any of the other ingredients in NITRADOS™ Tablets.
- suffer from lung disease.

- suffer from myasthenia gravis (severe muscle tiredness).
- are suffering from a psychiatric illness or a personality disorder.
- suffer from sleep apnoea (a condition where you stop breathing whilst asleep).
- suffer from head injury.
- have severe liver disorder.

Tell your doctor before you take NITRADOS™ if you:

- have a long-term lung, liver or kidney disease.
- suffer from depression.
- are suffering or have suffered from a mental illness.
- drink alcohol regularly. Do not drink alcohol while taking NITRADOS™.
- have a history of drug abuse or dependence.
- have glaucoma.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from the pharmacy, supermarket or health food shops.

Some medicines may interfere with the effect of NITRADOS™, particularly:

- Tranquillisers, antidepressants, hypnotics (sleeping tablets), anaesthetics or other medicines acting on the brain.
- Analgesics (pain killers), particularly opioid-based pain killers. It can make you very sleepy.
- Medicines used to treat allergies (antihistamines).
- Medicines used to treat epilepsy (anti-epileptics).

- Cimetidine (a medicine used to treat stomach problems).
- Rifampicin (an antibiotic).

Elderly patients should take extra care when taking NITRADOS™ Tablets as it can increase the risk of falls.

Pregnancy and breast-feeding

Tell your doctor if you are or intend to become pregnant. Your doctor will discuss the risks and benefits of taking this medicine with you.

If you need to take NITRADOS™ during late pregnancy or during labour, your baby may have floppiness, low body temperature, breathing and feeding difficulties. Your unborn baby may be at risk of developing dependency to this medicine and may be at some risk of developing withdrawal symptoms after birth.

Tell your doctor before you take NITRADOS™ if you are breastfeeding. Avoid taking NITRADOS™ if you are breast-feeding as it passes into the breast-milk.

Driving and using machines:

NITRADOS™ Tablets may cause blurred vision, dizziness and impaired concentration. This may affect your ability to operate machinery and drive. Do not drive or operate machinery while taking this medicine until you know how it affects you. Talk to your doctor or pharmacist if you have any concerns.

How to take NITRADOS™

Follow the directions given to you by your doctor carefully.

- The usual starting dose is 5mg. However, your starting dose may be different. Your doctor will prescribe the most suitable dose for you.
- Swallow the tablet with a glass of water.
- Take NITRADOS™ just before going to bed.
- Take NITRADOS™ exactly as your doctor has prescribed.
- Do not change the prescribed dose yourself. If you think the effect of your medicine is too strong or too weak, talk to your doctor.
- Treatment with NITRADOS™ should be short term. Treatment duration should not exceed 4 weeks.
- There is a risk of dependence with taking NITRADOS™. The risk increases with the dose and treatment duration.
- Never give your NITRADOS™ Tablets to other people. It may harm them even if their symptoms are the same as yours.

If you forget to take NITRADOS™, do not take a double dose to make up for the missed dose. Continue with the next dose when it is due.

If you take more NITRADOS™ than you should, contact your doctor, pharmacist or nearest hospital straight away.

When to stop taking NITRADOS™

Your doctor will advise you when to stop taking NITRADOS™. Do not stop taking NITRADOS™ Tablets suddenly. If you suddenly stop your treatment with NITRADOS™ you may experience

unpleasant withdrawal effects such as: depression, nervousness, rebound insomnia, irritability, perspiration and diarrhoea. In severe cases, changes in behaviour and convulsions may also develop. Withdrawal symptoms are less likely to occur if your dose is reduced gradually.

If you have been taking benzodiazepines for a long time, it will take a longer period of time to reduce your dose when you stop taking this medicine. You may need additional help. Your doctor will be able to discuss this with you.

Possible side effects of NITRADOS™

NITRADOS™, like all medicines, can cause side effects, although not everybody gets them.

You must inform your doctor immediately if the following symptoms occur:

- Changes in behaviour may occur. This may include aggression, excitement, confusion, restlessness, irritability, agitation, rages, nightmares, hallucinations and depression
- Jaundice - yellowing of the skin
- Allergic reaction – symptoms may include: rash, fainting, swelling of the tongue or throat, breathing difficulties
- Difficulty swallowing
- Increased dreaming or changes in sleep behaviour

Other side effects that may occur include:

- dose-related drowsiness
- unsteadiness
- muscular weakness
- poor muscle co-ordination
- changed libido
- loss of bladder control

- headache
- confusion
- vertigo
- dizziness
- visual disturbances
- stomach upset
- tiredness
- secretion of excess saliva and mucus

This is not a complete list of all possible side effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects you can help provide more information on the safety of this medicine.

How to store NITRADOS™ Tablets

Store at or below 30°C and protect from light. Keep this medicine out of the reach of children. Do not use this medicine after the expiry date (EXP) printed on the pack. Return any left-over medicine to your pharmacist.

Further information

NITRADOS™ white tablets are circular, scored on one side and company DP logo on the other.

NITRADOS™ contain 5 mg nitrazepam, **lactose** monohydrate, maize starch and magnesium stearate

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Date of revision: May 2017