

Nitrazepam 5mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Nitrazepam tablets are and what they are used for

Nitrazepam belongs to a group of medicines called benzodiazepines, which are tranquillisers (medicines that have a calming effect).

Nitrazepam tablets shorten the time taken to fall asleep and lengthens the duration of sleep.

Nitrazepam tablets are used for the short term treatment of sleeplessness (also known as insomnia) when it is severe.

Nitrazepam tablets help you to sleep but do not cure the underlying cause of your insomnia, which you should discuss with your doctor.

2 What you need to know before you take Nitrazepam tablets

Do not take Nitrazepam tablets and **tell** your doctor if you

- are **allergic** to nitrazepam or to any of the other ingredients of Nitrazepam tablets (these are listed in section 6, "Contents of the pack and other information")
- are **allergic** to any medicine known as a benzodiazepine (e.g. flurazepam, diazepam, chlordiazepoxide or temazepam).
- suffer from **lung disease**.
- suffer from **difficulty breathing** while awake or asleep.
- suffer from **myasthenia gravis** (a condition in which the muscles become weak and tire easily).
- are suffering from a **psychiatric illness** or a **personality disorder** (severe mental problems).
- have a severe **liver** condition.
- have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)

Nitrazepam tablets are not for use in anyone under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nitrazepam tablets if you:

- have problems with your heart and lungs, kidneys or liver
- suffer from depression (with or without anxiety) or have recently suffered the death of a close friend or relative.
- are suffering or have suffered from a mental illness, including a personality disorder.
- have abused alcohol or drugs. You must not drink alcohol or use drugs while taking Nitrazepam tablets.
- have low blood levels of a protein called albumin
- have a poor blood supply to the brain (arteriosclerosis)
- are elderly
- have epilepsy

Make sure that you can sleep without interruptions for 7 to 8 hours after taking the tablets.

Because Nitrazepam tablets relax the muscles, elderly patients should take extra care when they get up at night as there is a risk of falls and consequently of injuries including hip fractures.

Other considerations

- **Dependence** - when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse.
- **Tolerance** - if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.
- **Withdrawal** - treatment should be gradually withdrawn. Withdrawal symptoms occur with nitrazepam even when normal doses are given for short periods of time. See section 3, 'If you stop taking Nitrazepam tablets'.

Children

Do not give this medicine to children.

Other medicines and Nitrazepam tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- Antidepressants, other tranquillisers or sleeping pills, or other such medicines that act on the brain and nerves.
- Medicines used to relieve pain or anaesthetics.
- Antihistamines (used for treating allergies) that cause drowsiness.
- Lofexidine (to help relieve symptoms when you stop taking opioids), nabilone (to treat nausea and vomiting).
- Opioids (strong pain killers, medicines for substitution therapy and some cough medicines). Taking these medicines with Nitrazepam tablets increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Nitrazepam tablets together with opioids the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- Medicines for treating epilepsy (e.g. phenytoin and phenobarbital).
- Medicines that affect the liver (e.g. the antibiotic rifampicin).
- Moxonidine (to lower high blood pressure), muscle relaxants (e.g. baclofen, tizanidine). Taking these medicines with nitrazepam could make you very sleepy.

Nitrazepam tablets with alcohol

Do not drink alcohol while you are taking Nitrazepam tablets. Alcohol may increase the sedative effects of nitrazepam and make you very sleepy.

Pregnancy and breast-feeding

Pregnancy

Tell your doctor before taking Nitrazepam Tablets if you are pregnant, think that you are pregnant or intend to become pregnant during treatment. Your doctor will then decide whether you should take this medicine. If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness and breathing and feeding difficulties. Also, your unborn baby may be at risk of developing dependency to this medicine and after birth may be at some risk of developing withdrawal symptoms.

Breast-feeding

Tell your doctor before taking Nitrazepam Tablets if you are breast-feeding. Avoid taking Nitrazepam Tablets if you are breast-feeding as Nitrazepam passes into breast-milk.

Driving and using machines

Nitrazepam tablets may affect how your muscles work or may make you feel sleepy or forgetful. It may also impair your alertness (especially if you don't have 7-8 hours uninterrupted sleep). **Do not** drive or use any tools or machines if you are affected in this way.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Nitrazepam tablets contain lactose (a type of sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Nitrazepam tablets

Your doctor will find the lowest dose to control your symptoms. The dose that your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight.

Always take this medicine exactly as your doctor has told you. Do not change the prescribed dose yourself. You should check with your doctor or pharmacist if you are not sure how to take this medicine. If you think that the effect of your medicine is too weak or too strong, talk to your doctor.

Nitrazepam tablets are not for use in children.

The usual starting dose is 5 mg (one tablet). However, if you are elderly or suffer from a lung, liver or kidney condition, or are generally unwell, your starting dose will not usually be more than 2.5 mg (half a tablet).

You may not need to take this medicine every night.

Swallow the tablet(s) whole with water or another non-alcoholic drink.

Take the medicine just before going to bed. Make sure that you can sleep without interruptions for 7 to 8 hours after taking the tablets.

Treatment will not normally be continued for more than four weeks.

Nitrazepam tablets may become less effective if you take them for more than four weeks. If you think that your medicine is no longer working or your insomnia does not improve, you should consult your doctor. Also, you may become dependent on the tablets if you use them at high doses and for long periods. Therefore, Nitrazepam tablets are not suitable for long-term use and after a few weeks it is worth trying to get by without these tablets. This will help to prevent you becoming used to nitrazepam and reduce the risk of dependence.

Withdrawal symptoms may occur when you stop taking Nitrazepam tablets (see section below **If you stop taking Nitrazepam tablets**). Do not stop taking Nitrazepam tablets without speaking to your doctor.

If you take more Nitrazepam tablets than you should

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away. Signs of an overdose include slowing down of the nervous system (ranging from tiredness to coma) such as confusion, drowsiness, lack of co-ordination, reduced muscle tension, low blood pressure, slow heartbeat, breathing difficulties. In rare cases overdose may lead to coma (unrousable unconsciousness) and in very rare cases may lead to death.

If you forget to take Nitrazepam tablets

Do not take a double dose to make up for a forgotten dose. Instead you should simply continue with the next dose when it is due.

If you stop taking Nitrazepam tablets

Your doctor will advise you when to stop taking the tablets. Do not stop taking Nitrazepam tablets abruptly. You may experience withdrawal effects if your treatment is stopped suddenly. This is less likely if your dose is gradually reduced towards the end of your treatment.

Withdrawal symptoms may include: a recurrence of sleep problems, depression, nervousness, extreme anxiety, tension, restlessness, confusion, mood changes, irritability, sweating, diarrhoea, headaches, muscle weakness.

In severe cases the following symptoms may occur: changes in behaviour, numbness and tingling of the extremities, fits, over-sensitivity to light, noise and touch, hallucinations.

If you have taken benzodiazepines for a long time, the reduction in your dosage will be over a longer period of time than would normally be required when you stop taking this medicine. You may need additional help. Your doctor will be able to discuss this with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible Side Effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

Contact your doctor immediately if you notice the following:

- **Allergic reaction** – swelling of the face, lips, tongue or throat or difficulty breathing or swallowing.
- **Rash and other allergic skin reactions** including skin that is red or itchy, pale or red irregular raised patches with severe itching (hives), circular irregular red patches on the skin of the hands and arms (Erythema Multiforme) and severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome).
- **Disease of the liver** causing yellowing of the skin or whites of the eyes (jaundice).
- **Thoughts of suicide or suicidal behaviour.**

Changes in behaviour may occur rarely. These changes may include aggression, excitement, confusion, restlessness, agitation, irritability, rages, hallucinations, nightmares and depression. **If these behavioural symptoms occur, you must inform your doctor. He/she may want you to stop taking this medicine.**

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common: may affect up to 1 in 10 people

Dizziness, drowsiness, unsteadiness, loss of co-ordination, numbed emotions, reduced alertness, confusion, fatigue, headache, muscle weakness, double vision.

Uncommon: may affect up to 1 in 100 people

Sleeping problems including difficulty sleeping, reduced ability to concentrate, involuntary shakiness, muscle weakness.

Rare: may affect up to 1 in 1,000 people

Changes in the numbers and types of your blood cells, muscle cramps, changes in sex drive, disturbed vision, a spinning sensation (vertigo), low blood pressure, breathing problems, feeling sick, upset stomach, difficulty in passing water.

Not known: frequency cannot be estimated from the available data

Dependence, total or partial memory loss, depression, speech problems. You may become dependent on the tablets and find it difficult to stop taking them or feel you need to take them more often than necessary (see section 2 **Other Considerations**). If you stop taking the tablets suddenly, you may suffer from withdrawal reactions (see section 3 **If you stop taking Nitrazepam tablets**) with withdrawal symptoms).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Nitrazepam tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C in a dry place protected from light.

Do not use this medicine after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Nitrazepam tablets contain:

- The active substance is nitrazepam. Each tablet contains 5mg of nitrazepam.
- The other ingredients are lactose, magnesium stearate, maize starch and stearic acid.

What Nitrazepam tablets look like and contents of the pack

Nitrazepam tablets are white, circular, flat bevelled-edge uncoated tablets impressed "C" and the identifying letters "NA" on either side of a central division line on one face.

Pack size is 28 tablets.

Marketing Authorisation Holder and Manufacturer:
Accord, Barnstable, EX32 8NS, UK.

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