

Package leaflet: Information for the user

NITRAZEPAM 5 mg 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 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.

WHAT IS IN THIS LEAFLET:

- 1. What Nitrazepam is and what it is used for**
- 2. What you need to know before you take Nitrazepam**
- 3. How to take Nitrazepam**
- 4. Possible side effects**
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1. What Nitrazepam is and what it is used for

Nitrazepam is a sedative drug which is used in the short-term to help people sleep. It belongs to a group of drugs called benzodiazepines.

Nitrazepam is used for the short-term treatment of difficulty in sleeping, which is severe, disabling or causing extreme distress.

2. What you need to know before you take Nitrazepam

DO NOT take Nitrazepam if you:

- are allergic (hypersensitive) to nitrazepam, other benzodiazepines (e.g. temazepam or diazepam) or any of the other ingredients of this medicine (listed in section 6)
- suffer from severe lung problems
- suffer from problems such as phobias or obsessional behaviour
- suffer from myasthenia gravis, a specific condition causing severe muscle tiredness
- suffer from sleep apnoea (difficulty breathing while asleep)
- have severe liver disease
- are under the age of 12 years
- have acute porphyria
- are pregnant, or planning a pregnancy, unless you have discussed this with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- suffer from depression or depression with anxiety
- have kidney or liver problems
- have a history of drug dependence or alcoholism
- have been recently bereaved (if nitrazepam is taken to help sleep during periods of bereavement it may stop you coming to terms with your loss)
- suffer from hypoalbuminaemia (a condition where you have abnormally low levels of the protein albumin in your blood).

Other medicines and Nitrazepam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription as follows:

- sedatives
- anti-depressants (used to treat depression)
- monoamine oxidase inhibitors (MAOIs) e.g., tranylcypromine, phenelzine and isocarboxazid
- anti-histamines (used to treat allergies)
- anti-psychotics (used to treat mental problems)
- anaesthetics
- lofexidine (used to help relieve symptoms when you stop taking opioids)
- nabilone (used to treat nausea and vomiting)
- hypnotics (used to help you sleep)
- alpha blockers or moxonidine (used to treat high blood pressure)
- muscle relaxants, e.g. baclofen, tizanidine
- probenecid (used to treat gout)
- neuroleptics (e.g. chlorpromazine)
- pain killers
- theophylline
- anti-epileptic drugs e.g. hydantoin such as phenytoin, allobarbitol
- cimetidine (used to treat stomach ulcers)
- oestrogen containing contraceptives
- disulfiram (used to treat alcohol addiction)
- ritonavir (an antiviral)
- isoniazid (used to treat tuberculosis)
- rifampicin (an antibiotic, used to treat tuberculosis)
- levodopa (used to treat Parkinson's Disease).

Concomitant use of Nitrazepam Tablets and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) 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.

Important safety messages about Nitrazepam:

- When taking this medicine there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse, or suffer from a personality disorder.
- When stopping this medicine you may experience withdrawal effects (see section 3, **If you stop taking Nitrazepam**)
- Behavioural effects may occur while taking Nitrazepam (see section 4, **Possible Side Effects**).

Elderly patients

Elderly patients should be cautious whilst taking Nitrazepam, as there is a risk that they may fall whilst taking Nitrazepam, especially when they get up at night.

Nitrazepam with food, drink and alcohol

DO NOT drink alcohol whilst taking these tablets, as it may increase the sedative effect of the drug. Caffeine may reduce the effectiveness of these tablets.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding, you should not take Nitrazepam, unless you have discussed this with your doctor.

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, heart problems and breathing and feeding difficulties. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms.

Driving and using machines

Nitrazepam may cause drowsiness, forgetfulness, dizziness, blurred vision, reduced concentration or co-ordination. These effects may be increased if you have not had enough sleep, or if you have taken other medicines or drunk alcohol whilst taking Nitrazepam (see section Taking other medicines).

If affected, do NOT drive or operate machinery.

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 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Nitrazepam contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Nitrazepam

Always take this medicine exactly as your doctor has told you. Your doctor has decided the dose which is suited to you. Always follow your doctor's instructions and those that are on the pharmacy label. If you do not understand these instructions, or you are in any doubt, ask your doctor or pharmacist. You should continue to take these tablets for as long as your doctor tells you to.

The tablets should be swallowed preferably with a glass of water just before going to bed. To reduce the risk of loss of memory (amnesia), you should make sure that you are able to have an uninterrupted sleep of at least 7 hours after taking this medicine.

The recommended dose is:

- **Adults**
Usually one 5 mg tablet before going to bed.
If necessary your doctor may increase the dosage.
- **Children under 12 years of age**
Nitrazepam should not be used in children under 12 years of age.

- **Elderly or debilitated patients (including those with lung problems, kidney, or liver problems)**
The dose should not exceed half of the recommended adult dose.

You should not take these tablets for any longer than recommended by your doctor, as dependence may occur. It is generally recommended that nitrazepam should not be taken for longer than 4 weeks, including any tapering off period where the dose is gradually reduced.

If you see another doctor or go into hospital, let them or the staff know what medicines you are taking.

If you take more Nitrazepam than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause drowsiness, confusion, breathing difficulties, low blood pressure, difficulty in controlling movements and slurred speech. In children behavioural changes are likely to occur. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Nitrazepam

If you fall asleep without having taken a dose and wake up some hours later, do not take the missed dose. If necessary, return to your normal dose schedule the following night. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nitrazepam

After you have taken these tablets for the recommended time, your doctor may decide to stop your tablets as dependence may occur.

Do not stop taking your tablets suddenly, or without your doctor telling you, as you may suffer from withdrawal effects. If your doctor decides to stop your tablets, they will reduce the dose gradually to minimise any withdrawal effects.

- These effects may include depression, nervousness, irritability, diarrhoea, sweating, headaches, muscle weakness, muscle pain, confusion, extreme anxiety, tension, restlessness, mood changes and have difficulty sleeping.

If you experience any of these effects when you stop taking Nitrazepam, and you are concerned about them, ask your doctor for advice.

4. Possible side effects

Like all medicines, Nitrazepam can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you suffer from:

- behavioural changes such as restlessness, agitation, irritability, sweating, aggressiveness, delusions, excitement, rages, nightmares, hallucinations, confusion, psychiatric disorders and inappropriate behaviour, as your treatment may be stopped.

The most common side effects are:

- fatigue
- daytime drowsiness
- light-headedness.

These effects are often mild and usually wear off after a few days treatment.

If they are severe or last for more than a few days, tell your doctor.

The following have also been commonly reported:

- numbed emotion
- reduced alertness
- difficulty in controlling movements
- unsteadiness
- dizziness
- muscle weakness
- confusion
- memory loss
- dependence
- double vision
- slurred speech.

The following have been rarely reported:

- vertigo
- headache
- stomach upset
- low blood pressure
- cramps and muscle spasms
- visual disturbances
- allergic reactions, e.g. skin rashes or itching
- difficulties in passing urine
- changes in sex drive
- yellowing of the skin or the whites of the eyes (jaundice)
- blood disorders.

Loss of memory (amnesia) may occur, particularly if you are woken soon after taking the medicine.

Elderly patients, and those with kidney and liver damage are more likely to suffer the side effects listed above.

During treatment with Nitrazepam, pre-existing depression may be unmasked (you may begin to suffer symptoms of depression which were previously hidden).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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

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

These tablets should be stored in a cool place, protected from light in the package or container supplied. Do not transfer them to another container.

Do not use Nitrazepam after the expiry date that is stated on the outer packaging. 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 to protect the environment.

6. Contents of the pack and other information

What Nitrazepam Tablets contain:

- The active ingredient is nitrazepam 5 mg
- The other ingredients are maize starch, lactose monohydrate, pregelatinised maize starch, microcrystalline cellulose, magnesium stearate, and sodium starch glycolate.

What Nitrazepam Tablets look like and contents of the pack:

- Nitrazepam Tablets 5 mg are white, flat, bevel edged tablets. They are engraved “1N4” with a breakline on reverse
- The product is available in pack sizes of 7, 10, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 500, 12000 or 10 x 50 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

*OR

Marketing Authorisation Holder

TEVA UK Limited, Eastbourne, BN22 9AG.

Manufacturer

TEVA Pharmaceutical Works Private Limited Company
H-4042 Debrecen, Pallagi út 13., Hungary

**Only the actual site of batch release will appear on the printed version of the leaflet*

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