

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Nitrazepam 5mg Tablets

Nitrazepam Ph Eur

(referred to as Nitrazepam Tablets in the remainder of this leaflet)



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 please 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.

What is in this leaflet

1. What Nitrazepam Tablets are and what are they used for
2. What you need to know before you take Nitrazepam Tablets
3. How to take Nitrazepam Tablets
4. Possible side effects
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1. What Nitrazepam Tablets are and what are they used for

Nitrazepam, the active ingredient in these tablets, belongs to a group of medicines known as benzodiazepines which are tranquillisers (medicines that are known to have a calming effect). Nitrazepam shortens the time taken to fall asleep and lengthens the duration of sleep. This medicine should only be used in adults and the elderly for the short-term treatment of sleeplessness (also known as insomnia) when it is severe, causing distress and where daytime sleepiness is acceptable.

2. What you need to know before you take Nitrazepam Tablets

Do not take Nitrazepam Tablets and tell your doctor if you:

- are allergic (hypersensitive) to nitrazepam or any of the other ingredients in the tablets (listed in Section 6)
- are allergic (hypersensitive) to any of the group of medicines known as benzodiazepines (e.g. flurazepam, diazepam, chlordiazepoxide, or temazepam)
- have severe breathing problems or severe problems with your lungs
- suffer from acute porphyria (light-sensitive skin rash)
- suffer from myasthenia gravis (abnormal muscle fatigue)
- suffer from sleep apnoea syndrome (a temporary breathing stoppage during sleep)
- suffer from severe liver disease
- are suffering from a mental illness or a personality disorder (phobia or obsession).
- have rare hereditary galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption.

Do not take Nitrazepam Tablets If any of the above applies to you, speak to your doctor before taking these tablets.

Warnings and precautions

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

- suffer from depression or worry caused by depression without the use of other medicines to treat these conditions
- have recently suffered the death of a close friend or relative
- have insomnia, as the reason for this condition should be looked in to
- have taken nitrazepam before or have been taking it for a long period as the medicine may become less effective or you could become dependent on it
- have a history of regularly drinking alcohol or use of recreational drugs. You must not drink alcohol or take recreational drugs whilst taking Nitrazepam Tablets
- want to stop taking your medicine as you may suffer withdrawal if you stop taking this medicine suddenly
- cannot have seven to eight hours unbroken sleep. If you are woken from sleep within this time you may suffer from loss of memory for a short while
- have a personality disorder, as side effects (including suicidal wishes) may become increased
- are elderly or infirm as these tablets relax the muscles and may increase the risk of falls
- have low blood levels of a protein called albumin (hypoalbuminaemia)
- have epilepsy
- have heart, lung, kidney or liver disease.

Children

Do not give this medicine to children under the age of 12.

Other medicines and Nitrazepam Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is extremely important; as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

Examples of medicines that can affect Nitrazepam Tablets are:

- medicines that act on the brain or nerves such as antidepressants, anaesthetics, other tranquilisers, sleeping pills and hypnotics
- drugs used to relax muscles, such as baclofen or tizanidine
- probenecid, used to treat gout
- drugs used to treat high blood pressure, such as moxonidine or medicines called alpha blockers
- antihistamines (that make you feel sleepy), used for hayfever and other allergies
- drugs used for alcohol or drug dependence such as disulfiram, or lofexidine.

Taking nitrazepam with the medicines listed above could make you very sleepy.

- Strong pain killers may give you a heightened sense of well being when taken with this medicine.
- Drugs used to treat epilepsy, as nitrazepam can affect the blood levels of these medicines.
- Drugs related to the substance dopamine, such as Levodopa, a drug used in the treatment of Parkinson's disease. Nitrazepam may cause these medicines to not work as well as usual.
- Caffeine (in tea, coffee and some soft drinks) and theophylline, used for asthma and bronchitis as these may reduce the sedative effect of your medicine.
- Cimetidine (for ulcers), oral contraceptives, drugs used to treat infections, called antivirals and antibacterials such as ritonavir, or isoniazid (to treat tuberculosis). These may cause nitrazepam to be removed from the body more slowly than usual.
- Rifampicin (an antibiotic). This may cause nitrazepam to be removed from the body more quickly than usual.

Taking Nitrazepam with alcohol

Do not drink alcohol while you are taking Nitrazepam Tablets. Alcohol will increase the sedative effect of this medicine and can be dangerous.

Pregnancy and breastfeeding:

You should not take Nitrazepam tablets if you are pregnant, planning to become pregnant or are breast feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If your doctor has decided that you should take this medicine during the late stages of pregnancy or labour, your baby might have low body temperature, floppiness, breathing, or feeding difficulties. Your baby may develop dependency to this medicine and may be at risk of developing withdrawal symptoms.

Nitrazepam passes into breast-milk; therefore, do not breast-feed if you are taking this medicine. Your doctor will be able to discuss this with you.

Driving and using machinery

Nitrazepam may make you sleepy or affect your concentration. This may affect your performance at skilled tasks e.g. driving and operating machinery. If you have not had enough sleep it is possible that you may feel less alert than usual. Do not drive or use machinery if you feel any of these effects.

This medicine can affect your ability to drive as it may make you feel 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

Continued overleaf...

Nitrazepam Tablets contain lactose

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you are intolerant to some sugars you should contact your doctor before taking this medicine.

3. How to take Nitrazepam Tablets

- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight.
- **Adults:** The normal recommended starting dose is 5 mg.
- **Elderly, weak or less mobile patients, or those suffering from a lung, liver or kidney condition:** your doctor may prescribe a lower dose for example 2.5 mg.
- Your doctor will find the lowest dose to control your symptoms. You may not need to take this medicine every night. Treatment will be as short as possible to improve your symptoms and will not normally be continued for more than four weeks.
- Take the medicine just before going to bed and **making sure you can sleep for 7-8 hours without being disturbed** after taking the tablets.
- Swallow the whole tablet with water or another non-alcoholic drink without crushing or chewing. Do not change the prescribed dose yourself (see 'If you stop taking Nitrazepam' below). If you think the effect of your medicine is too weak or too strong, talk to your doctor.

Do not give to children under the age of 12 years.

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. Take the medicine, its container, and this leaflet with you.

If you forget to take Nitrazepam Tablets:

If you forget to take one dose, you should never make up for the missing dose by doubling the dose next time. 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 medicines. Withdrawal symptoms may occur when you stop taking Nitrazepam tablets. Please remember that it is not suitable for long-term use. The beneficial effects of this medicine decrease with long-term use and could cause dependency. Therefore you should always follow the dosing instructions your doctor gives you to ensure that long-term use is avoided.

Do not stop taking Nitrazepam tablets abruptly, you may experience withdrawal effects which may include:

- depression
- headaches
- muscle weakness
- nervousness
- extreme anxiety
- tension
- restlessness
- confusion
- mood changes
- a recurrence of sleep problems
- irritability
- sweating
- diarrhoea

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

In rare cases where patients have taken benzodiazepines for a long time, a longer period will be needed over which their dosage will be reduced.

Special help may also be needed. 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 serious side effects as you may need additional treatment:

- Allergic reaction (hypersensitivity) – 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, sore throat, fatigue (Stevens-Johnson syndrome).

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

Common (occurs in less than 1 in 10 users)

- Dizziness, feeling unsteady, loss of co-ordination
- feeling of emptiness or numb
- feeling tired, drowsiness, less alert.

Uncommon (occurs in less than 1 in 100 users)

- Confusion
- sleeping problems including difficulty sleeping
- finding it harder to concentrate
- involuntary shaking
- muscle weakness.

Rare (occurs in less than 1 in 1,000 users)

- Changes in the number and types of blood cells (shown in blood tests)
- muscle cramps, muscle spasm of neck, shoulders and body
- change in sex drive
- headache, a spinning sensation (vertigo)
- visual problems
- low blood pressure (feeling light headed, fainting)
- breathing problems
- feeling sick (nausea), upset stomach
- liver problems causing yellowing of the skin or whites of the eyes (jaundice)
- difficulty in passing water.

The following rare side effects may be observed more frequently in elderly patients

- Changes in behaviour such as excitement, irritability, aggressiveness, believing something that is not true (delusions), rage, nightmares, seeing hearing or feeling things that are not there (hallucinations), disturbances in thinking (depression, mood swings, paranoia).

Unknown frequency

- Dependence
- Partial or total memory loss (the risk increases with higher doses)
- depression with or without suicidal tendencies
- speech problems
- double vision.

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. If you stop taking the tablets suddenly you may suffer from withdrawal reactions (see Section 3 'If you stop taking Nitrazepam tablets' for withdrawal symptoms).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on the leaflet. You can report side effects directly via www.mhra.gov.uk/yellowcard. 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.

- Do not use this medicine after the expiry date which is stated on the pack.
- The tablets should be stored below 25°C and protected from light.
- 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 help protect the environment.

6. Contents of the pack and other information

What Nitrazepam Tablets contain

The active ingredient is nitrazepam. Each tablet contains 5 mg of nitrazepam.

The other ingredients are lactose monohydrate, maize starch, talc, stearic acid.

What Nitrazepam Tablets look like and contents of the pack

Nitrazepam Tablets are white, round with a score-line across one side.

Nitrazepam Tablets are available in packs of 28 and 56 tablets packed into blisters.

Marketing Authorisation Holder and Manufacturer

Esteve Pharmaceuticals Ltd, The Courtyard Barns, Choke Lane, Cookham Dean, Maidenhead, Berkshire, SL6 6PT

This leaflet was last revised in May 2022.