

Nitrazepam 5 mg, tablets

What is this medicine used for?

Nitrazepam belongs to the group of so-called benzodiazepines. Benzodiazepines are medicines with a calming, sleep-inducing, and muscle-relaxing effect. Nitrazepam is used as a sleeping aid.

When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to one of the substances in this medicine. You can find these substances.
- You are hypersensitive to other benzodiazepines or benzodiazepine-like substances. Perhaps you are aware of this due to an earlier investigation of hypersensitivity. Hypersensitivity usually manifests itself in the form of skin reactions, such as rash, hives, or itching.
- You have a severe muscle disease (myasthenia gravis). Nitrazepam can cause muscle relaxation.
- You have severe breathing problems.
- You have the so-called "sleep apnea syndrome" (a brief interruption of breathing during sleep, often accompanied by snoring).
- You have a severe liver disease.

When should you be extra careful with this medicine?

Habituation: After repeated use for several weeks, the sleep-inducing effect may diminish.

Dependency: Treatment with Nitrazepam and other benzodiazepines can lead to the user having the tendency to continue taking Nitrazepam and to develop a form of "mental and physical addiction": a difficult-to-control urge to repeatedly use more tablets. This tendency increases with prolonged use, high doses, and in patients with alcohol and drug abuse.

If the tablets are then suddenly and completely stopped, withdrawal symptoms can occur, such as extreme anxiety, tension, headache, muscle pain, restlessness, confusion, and irritability. Sometimes, in that situation, symptoms of an even more serious nature occur, such as self-alienation, loss of reality, altered hearing, numbness and tingling in the limbs, delusions (hallucinations), seizures (epilepsy), and hypersensitivity to light, sound, and touch. These symptoms are the result of physical dependence.

It is therefore advisable not to stop the use abruptly but to gradually reduce the dose.

Memory loss: A phenomenon that can occur during treatment with Nitrazepam and similar drugs is memory loss for several hours immediately following tablet intake. This is more likely to occur with insufficient sleep. Therefore, make sure that 7 to 8 hours of sleep time is available.

Mental disorders: It is known that during the use of benzodiazepines, symptoms such as restlessness, excitement, irritability, aggression, delusions, outbursts of anger, nightmares, delusions, mental illnesses, maladaptive behavior, and other behavioral disorders can occur. If this is the case with you, stop taking Nitrazepam and consult your doctor.

These symptoms are more common in children and the elderly.

Sleepwalking and other associated behavior such as sleep driving, preparing and eating food, having phone conversations, or engaging in sexual activity, with memory loss for the event.

Adverse reactions have been reported in patients who have used nitrazepam and were not fully awake. The use of nitrazepam in combination with alcohol and other drugs appears to increase the risk of this behavior. Additionally, using more nitrazepam than the recommended maximum dose also increases the risk of this behavior.

Nitrazepam should be used with caution and at a low dosage in elderly patients. This also applies to individuals with chronic respiratory diseases due to the risk of reduced breathing. These types of medications should not be used as the sole medication in the treatment of severe mental illnesses (psychoses, depression, and anxiety associated with depression) due to the risk of worsening symptoms. Nitrazepam should not be used in cases of severe liver disease.

In cases of chronic liver or kidney disease, the dosage should be reduced. If you have a history of alcohol or drug dependence, Nitrazepam should be used with the utmost caution.

Benzodiazepines are not recommended as a first-line treatment for psychoses (mental disorders). Nitrazepam and other benzodiazepines are not recommended for the treatment of sleep disorders in children, unless the need has been evaluated by the treating physician. In such cases, the treatment duration should be as short as possible.

In rare cases, excessive secretion from the bronchi and salivation may occur in children and elderly bedridden patients, which may lead to breathing difficulties or pneumonia. Contact your doctor or pharmacist before using this medication.

Are you taking any other medications? If you are taking other medications, or have recently taken them, or if you may use other medications in the near future, tell your doctor or pharmacist.

When Nitrazepam is used in combination with other medications, it may affect their efficacy. Elderly patients are particularly sensitive to interactions with other medications.

Alcohol and medications for mental disorders, such as neuroleptics (for severe mental illnesses), sleeping pills and sedatives, antidepressants, certain painkillers (opioids), medications for epilepsy, anesthesia, and some antihistamines (allergy medications) are particularly important, as they can amplify the effect of Nitrazepam. The aforementioned painkillers can enhance the sense of unreal and excessive well-being and optimism (euphoria) that can occur with the use of Nitrazepam, increasing the reported danger of addiction to this type of medication.

The elimination of benzodiazepines can be influenced by substances such as cimetidine (inhibitor of acid formation in the stomach), rifampicin (used for tuberculosis), and 'the pill'. The reliability of 'the pill' is not affected by benzodiazepines.

It is also known that the breakdown of Nitrazepam may be delayed by medications that have a strong effect on the liver.

Concurrent use of Nitrazepam with opioids (strong painkillers, substitution therapy medications, and some cough medicines) increases the risk of drowsiness, breathing problems, coma, and can be life-threatening. Therefore, Nitrazepam should only be used with opioids when other treatments are not possible. If your doctor still decides to prescribe Nitrazepam concurrently with opioids, the dosage and duration of the concurrent treatment should be limited by your doctor.

Tell your doctor all the opioids you use and follow your doctor's recommended dosage carefully. It is recommended that you inform your friends and family of the above-mentioned signs and symptoms. Contact your doctor as soon as you experience such symptoms.

What should you be aware of when consuming alcohol: The use of alcohol during treatment is not recommended because this medication and alcohol can enhance each other's effects.

Pregnancy, breastfeeding, and fertility: Are you pregnant, think you might be pregnant, want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

Pregnancy: There is insufficient data on the use of Nitrazepam during pregnancy to assess the possible harmful effects. The use of Nitrazepam during pregnancy is strongly discouraged because adverse effects on the child can result.

Breastfeeding: There is insufficient data on the use of Nitrazepam during breastfeeding to assess the possible harmful effects. Because benzodiazepines pass into breast milk, Nitrazepam should not be used during breastfeeding.

Driving and using machinery: The calming effect of Nitrazepam, memory loss, reduced concentration, and reduced muscle function can adversely affect driving ability and the ability to operate machinery. This risk is greater when there is insufficient sleep and/or alcohol use.

If you are in a job that requires constant alertness, you should be aware that using Nitrazepam may prevent you from performing your work to the highest standards. The same applies if you need to be alert in order to make important decisions or use your limbs without hindrance, such as when driving or operating machinery. Nitrazepam contains lactose. Each tablet contains 353.6 mg of lactose. If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist. In general, treatment should not last longer than two weeks, sometimes four weeks. In certain cases, your doctor may decide to extend the treatment. The treatment should begin with the lowest possible recommended dose. Your doctor will monitor the effects of the treatment at the beginning and may adjust the dosage if necessary. In most cases, the prescribed amount for adults is one tablet of Nitrazepam, 5 milligrams, once a day. This dose can be reduced or increased to 10 milligrams. For elderly patients and patients with impaired liver and/or kidney function, the normal dose is generally half to one tablet. The tablet can be divided into equal doses. A lower dose is also recommended for patients with chronic respiratory diseases.

Method of use: The tablets can be taken whole or as half tablets with some water or dissolved in water before going to sleep.

What if you use too much of this medicine: If you have taken too much of this medicine, you should immediately contact a doctor or go to the emergency department of the nearest hospital. Symptoms of benzodiazepine overdose usually include drowsiness and coma. In mild cases, the symptoms may include drowsiness and confusion. In more severe cases, and especially when taken with certain other medicines and alcohol, symptoms may occur such as coordination problems (ataxia) for example staggering gait, low blood pressure (hypotension), decreased breathing (respiratory depression), coma and, very rarely, death.

Treatment: If possible, it is recommended to let the patient, if conscious, vomit while waiting for help.

Did you forget to use this medication: If you miss a dose, never compensate by taking a double dose the next time. In such a case, wait until the time for the next dose, and then continue according to the normal schedule.

If you stop using this medication: The treatment should be as short as possible and generally does not last longer than four weeks. Only your doctor can decide if the treatment should last longer.

Treatment with Nitrazepam should not be stopped suddenly because stopping taking the tablets suddenly can lead to a worsening of the sleep disorders for which Nitrazepam was actually prescribed. Mood swings, anxiety, and restlessness may also occur in that case. This does not mean that the treatment has been terminated too early!

It is advisable to gradually use a lower dosage of Nitrazepam in consultation with your doctor. Any renewed use of Nitrazepam or another sleeping pill should only take place after consulting your doctor.

Do you have any other questions about the use of this medication? Then please contact your doctor or pharmacist.

Possible Side Effects

Like any medication, this medication can have side effects, although not everyone experiences them.

The frequencies of the side effects mentioned below are classified as follows:

- Very common: in more than 1 in 10 patients
- Common: in 1 to 10 out of 100 patients
- Uncommon: in 1 to 10 out of 1,000 patients
- Rare: in 1 to 10 out of 10,000 patients
- Very rare: in less than 1 in 10,000 patients
- Unknown: cannot be determined with available data.

Blood and lymphatic system: Psychological disorders

Blood disorders: Restlessness, agitation, irritability, aggression, delusions, outbursts of anger, nightmares, perceptions of things that are not there (hallucinations), severe mental illness where control over one's behavior and actions is disturbed (psychosis), maladaptive behavior and other behavioral disorders*. Mood swings, anxiety, flat affect. Memory loss, sadness (depression). Sleepwalking (somnambulism).

Blood and lymphatic system: Nervous system Sleep disorders.

Blood disorders

Insomnia, dependence on the medication (both physical and psychological). Daytime sleepiness, decreased alertness, headaches, dizziness**. Coordination problems (ataxia), for example staggering.

- **Blood and lymphatic system:** Eyes
- **Blood disorders:** Visual disturbances. Double vision**.
- **Blood and lymphatic system:** Blood vessels
- **Blood disorders:** Low blood pressure hypotension).
- **Blood and lymphatic system:** Respiration
- **Blood disorders:** Suppression of breathing, secretion from the lungs, aspiration, pneumonia.
- **Blood and lymphatic system:** Stomach and intestines
- **Blood disorders:** Excessive salivation, disturbances of the stomach and intestines.
- **Blood and lymphatic system:** Liver and gallbladder
- **Blood disorders:** Jaundice.
- **Blood and lymphatic system:** Skin
- **Blood disorders:** Skin reactions.
- **Blood and lymphatic system:** Bones and muscles
- **Blood disorders:** Muscle weakness**.
- **Blood and lymphatic system:** Urinary tract and kidneys
- **Blood disorders:** Retention of urine (urinary retention).
- **Blood and lymphatic system:** genital organs and breasts
- **Blood disorders:** Decreased sex drive (decreased libido).
- **Blood and lymphatic system:** General
- **Blood disorders:** Confusion, fatigue.

These types of effects occur more frequently in children and the elderly.

** These symptoms occur mainly at the beginning of treatment and usually disappear after continued use.

If you experience a lot of any of the side effects, or if you experience a side effect that is not listed in this leaflet, contact your doctor or pharmacist. You can then discuss with him or her to what extent continued treatment with Nitrazepam is appropriate.

How to store this medicine?

Store below 25°C. Store in the original packaging to protect against moisture.

Keep out of sight and reach of children.

Do not use this medicine after the expiry date printed on the packaging after EXP. The expiry date is stated as a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be disposed of in a responsible manner and will not harm the environment.