

Nitrazepam Mixture 2.5 mg/5 ml Oral Suspension BP

nitrazepam

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.

What is in this leaflet:

1. What Nitrazepam Mixture Oral Suspension is and what it is used for
2. What you need to know before you take Nitrazepam Mixture Oral Suspension
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1. What Nitrazepam Mixture Oral Suspension is and what it is used for

Nitrazepam Mixture Oral Suspension belongs to a group of medicines known as benzodiazepines, which are tranquillisers (medicines that have a calming effect). Nitrazepam shortens the time taken to fall asleep and lengthens the duration of sleep.

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

Nitrazepam Mixture Oral Suspension helps you to sleep but does 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 Mixture Oral Suspension

Do not take Nitrazepam Mixture Oral Suspension

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

Warnings and precautions

Take special care with Nitrazepam Mixture Oral Suspension

Talk to your doctor or pharmacist before taking Nitrazepam Mixture Oral Suspension

- if you have a long-term lung, liver or kidney disease;
- if you suffer from depression or worry caused by depression, or have recently suffered the death of a close friend or relative;
- if you are suffering or have suffered from a mental illness;
- if you notice that this medicine is not working as well as it did when first starting treatment;
- if you are not able to have 7 or 8 hours of unbroken sleep. If you are woken from sleep within this time you may suffer from a loss of memory for a short while;
- if you experience changes in behaviour such as aggression, confusion, restlessness, agitation, irritability, rages, delusion (a fixed irrational idea not shared by others), nightmares, hallucinations, psychoses (severe mental condition in which the person loses contact with reality and is unable to think and judge clearly) or inappropriate behaviour. If these behavioural changes occur your doctor may want you to stop taking this medicine;
- if you have abused alcohol or drugs. You must not drink alcohol or use drugs while taking nitrazepam;
- if you are pregnant or breast-feeding.

Because nitrazepam relaxes 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.

Children

Nitrazepam Mixture Oral Suspension is not for use in anyone under 18 years of age.

Other medicines and Nitrazepam Mixture Oral Suspension

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.

Concomitant use of Nitrazepam Mixture 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 Mixture 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.

Also tell your doctor if you are taking any of the following medicines:

- Antidepressants, other tranquillisers or sleeping pills, or other such medicines that act on the brain and nerves.
- Medicines used to relieve pain (eg. codeine) or anaesthetics.
- Antihistamines (used for treating allergies) that cause drowsiness (e.g. chlorphenamine).

- Medicines for treating epilepsy (e.g. phenytoin, carbamazepine and phenobarbital).
- Medicines that affect the liver (e.g. the antibiotic rifampicin).
- Cimetidine used to treat stomach ulcers, (as this can cause nitrazepam to be removed more slowly than usual from the body).
- Probenecid used to treat gout (painful inflammation of the joints).
- Levodopa (to treat Parkinson's disease) as nitrazepam may cause levodopa to not work as well as it should.

Nitrazepam Mixture Oral Suspension with alcohol

Do not drink alcohol when taking Nitrazepam Mixture Oral Suspension. Alcohol can increase the effects of nitrazepam and this can be dangerous.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you and your doctor decide that you should take this medicine towards the end of your pregnancy (or during labour) this may harm your baby. The baby may have a low temperature, floppiness, and breathing problems or difficulty in feeding.

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.

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

Driving and using machines

Nitrazepam Mixture Oral Suspension may cause side effects such as reduced alertness, confusion, tiredness, dizziness, poor muscle co-ordination and double vision. This may affect your ability to drive and operate machinery. Do not drive or operate machinery if you experience any of these side effects.

This medicine can affect your ability to drive.

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.

There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>.

Nitrazepam Mixture Oral Suspension contains sucrose and sodium

This medicine contains 2 g of sucrose per 5 ml of oral suspension. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. May be harmful to teeth.

This medicine contains 7.5 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.37% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Nitrazepam Mixture Oral Suspension

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 Nitrazepam Mixture Oral Suspension 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.

The carton contains a bottle and a 20 ml measuring cup graduated to indicate 2.5 ml, 5 ml, 10 ml and 20 ml doses. Ensure you fill the cup to the correct graduation line.

Wash the cup in warm water immediately after use and allow to dry.

- The usual dose for adults is 10 ml. Sometimes, if this dose doesn't work, the doctor may increase it to 20 ml.
- Older people and patients with liver, kidney or breathing problems should take half the adult dose - 5 ml. Sometimes, if this dose doesn't work, the doctor may increase it to 10 ml.
- Take the medicine just before going to bed. Before you take Nitrazepam Mixture Oral Suspension make sure you have enough time for 7-8 hours sleep.
- The doctor may tell you not to take the medicine every night.
- If you forget to take Nitrazepam Mixture Oral Suspension and remember too late for 7 to 8 hours sleep, do not take any Nitrazepam Mixture Oral Suspension until the next night.

Nitrazepam Mixture Oral Suspension is not for use in children.

Nitrazepam Mixture Oral Suspension may become less effective if you take it 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 Nitrazepam Mixture if you use it at high doses and for long periods. Therefore, Nitrazepam Mixture Oral Suspension is not suitable for long-term use and after a few weeks it is worth trying to get by without it.

This will help to prevent you becoming used to Nitrazepam Mixture Oral Suspension and reduce the risk of dependence.

Duration of treatment: Normally treatment lasts from a few days to two weeks with a maximum of 4 weeks.

To stop treatment, the doctor will probably advise you how to reduce your dose slowly until you stop. Withdrawal symptoms may occur when you stop taking Nitrazepam Mixture Oral Suspension (see section below **Stopping Nitrazepam Mixture Oral Suspension and Withdrawal Symptoms**).

Do not stop taking Nitrazepam Mixture Oral Suspension without speaking to your doctor.

If you take more Nitrazepam Mixture Oral Suspension than you should

If you take too much oral suspension or someone else accidentally takes your medicine, contact a doctor **immediately**.

Symptoms of overdose may be:

- Drowsiness
- Confusion
- Difficulty in speaking or unclear speech
- Lack of energy/tiredness
- Difficulties coordinating arms and legs
- Low muscle tone
- Low blood pressure
- Very slow and/or shallow breathing
- Rarely coma

If you forget to take Nitrazepam Mixture Oral Suspension

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.

Stopping Nitrazepam Mixture Oral Suspension and Withdrawal Symptoms:

This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly. If you stop taking this medicine suddenly you may experience the following withdrawal effects:

- 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking the medicine and/or seek urgent medical advice immediately if you notice the following:

- Serious allergic reactions which may include swelling of the face including throat and tongue, breathing difficulties/ wheezing, feeling faint, weak and or collapse.
- Allergic skin reaction including skin that is rean or itchy, pale or red irregular raised patched 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).

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.

Common side effects:

- drowsiness during the day
- a feeling of emptiness
- reduced alertness
- confusion
- tiredness
- headache
- dizziness
- muscle weakness
- poor muscle co-ordination
- double vision
- depressed state

Rare side effects:

- giddiness
- reduced blood pressure
- stomach upsets
- skin rashes
- changes in your vision other than double vision
- changes in the level of sexual desire
- inability to pass urine
- spinning sensation
- nausea
- speech disorder

Frequency unknown:

- an abnormality of the blood (blood dyseranias)
- yellowing of the eyes and skin (jaundice)
- trouble falling and/or staying asleep, decline in mental abilities (memory and thinking skills), dependence (at regular dose) – You may become dependent on the medicine and find it difficult to stop taking it. If you stop taking Nitrazepam suddenly, you may suffer from withdrawal reactions (see section 3
- unsteadiness, reduced muscle movement, tremor, memory loss, epileptic fits
- breathing problems, increased bronchial secretions.
- muscle cramps
- risk of falls and consequently fractures in the elderly
- irritability, rebound effect

If you are woken up soon after taking the medicine your memory may be temporarily affected.

If you are an elderly patient, you may be more susceptible to side effects. If this happens, tell your doctor and he/she may decide to change your dose.

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 Mixture Oral Suspension

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

Store in a refrigerator (2°C - 8°C). Store in the outer carton in order to protect from light. Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. 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 Mixture Oral Suspension contains

The active substance is nitrazepam. There are 2.5 mg of nitrazepam in each 5 ml.

The other ingredients are sucrose, microcrystalline cellulose, carboxymethyl cellulose sodium, a preservative (mixed esters of p-hydroxybenzoic acid), cherry flavour and water (see end of Section 2 for further information about sucrose and sodium).

What Nitrazepam Mixture Oral Suspension looks like and contents of the pack

Nitrazepam Mixture Oral Suspension is a white to off-white suspension with a cherry odour.

It is available in a 70 ml amber glass bottle with a tamper-evident child-resistant polypropylene (PP) cap with and a polyethylene (PE) liner and a 20 ml measuring cup (polypropylene) with increments in the range of 2.5 ml to 20 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

Manufacturer:

Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, The Netherlands.

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