confusion, restlessness, agitation, irritability, rages, hallucinations, nightmares and depression.
If these behavioural symptoms occur, you must inform your doctor. They 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, loss of co-ordination, numbed emotions, reduced alertness, confusion, fatigue, headache, muscle weakness, double vision, depressed state.

Rare: may affect up to 1 in 1,000 people
Changes in the level of sexual desire, changes in your vision (other than double vision), a spinning sensation (vertigo), low blood pressure, feeling sick, abdominal discomfort, skin rashes, difficulty in passing urine, speech disorder.

Not known: frequency cannot be estimated from the available data
An abnormality of the blood (blood disorder), emotional disorder, delirium, trouble falling and/or staying asleep, decline in mental abilities (memory and thinking skills) dependence and addiction (see section "**How do I know if I am tolerant or addicted?** "), unsteadiness, reduced muscle movement, tremor, memory loss, epileptic fits, breathing problems, increased bronchial secretions, muscle cramps, a risk of falls and consequently fractures in the elderly, irritability, rebound effect.

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

Drug Withdrawal
When you stop taking nitrazepam tablets, you may experience drug withdrawal symptoms. See Section 3, **'If you stop taking Nitrazepam tablets'.**

How do I know if I am tolerant or addicted?
If you notice any of the following signs whilst taking Nitrazepam tablets, it could be a sign that you have become addicted.
- you need to take the medicine for longer than advised by your doctor
- you feel you need to use more than the recommended dose
- you are using the medicine for reasons other than prescribed
- when you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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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, Barnstaple, EX32 8NS, UK.

Date of Revision: November 2025

accord

Package leaflet: Information for the patient

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.
- This medicine contains nitrazepam, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly.

What is in this leaflet

1 **What Nitrazepam tablets are and what they are used for**
2 **What you need to know before you take Nitrazepam tablets**
3 **How to take Nitrazepam tablets**
4 **Possible side effects**
5 **How to store Nitrazepam tablets**
6 **Contents of the pack and other information**

1 What Nitrazepam tablets are and what they are used for
This medicine has been prescribed for you for the short-term treatment of sleeplessness (also known as insomnia) when it is severe. It contains nitrazepam which belongs to a class of medicines called benzodiazepines.
Nitrazepam shortens the time taken to fall asleep and lengthens the duration of sleep.
Nitrazepam tablets help you to sleep but do not cure the underlying cause of your insomnia, which you should discuss with your doctor.
This medicine has been prescribed to you and should not be given to anyone else.
Nitrazepam tablets can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking them or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

2 What you need to know before you take Nitrazepam tablets
Do not take Nitrazepam tablets if you:
- are **allergic** to nitrazepam or to any of the other ingredients of this medicine (listed in section 6)
- 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

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 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 low blood levels of a protein called albumin
- are elderly
- have epilepsy
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more Nitrazepam tablets to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. See Section 3, **'If you stop taking Nitrazepam tablets'.** Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine.

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It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else.
Taking higher doses or more frequent doses of benzodiazepines may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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.

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, barbiturates, antipsychotics, hypnotics, anxiolytics, tranquillisers or sleeping tablets, 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 (e.g. chlorphenamine).
- 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, cimetidine, some azole antifungal agents, omeprazole; medicines used to treat stomach problems, disulfiram and St John's wort).
- Sodium oxybate used in patients with narcolepsy.
- Theophylline or aminophylline; medicines to make breathing easier.
- 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.
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 prescribed will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight.

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Your doctor should have discussed with you how long the course of will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your doctor will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

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).
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. You may not need to take this medicine every night.
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
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your doctor will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

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,

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