

Diazepam 5 mg rectal solution

Diazepam 10 mg rectal solution

Diazepam

The name of your medicine is Diazepam rectal solution, which will be referred to as 'Diazepam' or 'Diazepam solution' throughout this leaflet.

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Diazepam is and what it is used for
2. What you need to know before you use Diazepam solution
3. How to use Diazepam solution
4. Possible side effects
5. How to store Diazepam solution
6. Contents of the pack and other information

1. What Diazepam is and what it is used for

Diazepam belongs to a group of medicines known as benzodiazepines, which are used as sedatives and anticonvulsants (to control fits), or to relax tense muscles.

Diazepam is used:

- to control epileptic or febrile convulsions (fits)
- for sedation before minor surgical or dental procedures
- for muscle spasms in tetanus
- for severe, disabling, or extremely distressing anxiety or agitation

Diazepam solution may be used as above when an injection is not practical or not wanted.

Diazepam solution may be useful for the immediate treatment of convulsions in children.

2. What you need to know before you use Diazepam solution

Do not use Diazepam solution

- if you are **allergic** to **diazepam** or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue.
- if you have **myasthenia gravis** (very weak muscles).
- if you **suffer from sleep apnoea** (temporary stopping of breathing during sleep).
- if you have a **severe liver disorder**.
- if you have a **severe breathing disorder**.

Diazepam should **not be used for premature babies**.

Warnings and precautions

Talk to your doctor before using Diazepam solution

- if you have a **kidney or liver disorder**.
- if you have a **breathing disorder**.
- if you have a **poor blood supply to the brain or any brain damage**.
- if you **have a history of alcohol or drug abuse**.
- if you **are suffering from mental illness** (such as depression, phobia or obsession).

Patients in shock may be treated with Diazepam only if measures are concurrently undertaken to correct the volume deficiency.

Diazepam solution should not be taken at the same time as alcohol and/or medicines with a depressant effect on the central nervous system. If taken at the same time, the effect of Diazepam can be enhanced and may lead to unconsciousness and depression of the cardiovascular function and/or breathing, requiring emergency treatment.

If you received Diazepam for e.g. minor surgical or dental procedures, you should only go home accompanied by someone else.

Development of tolerance

Following repeated use of Diazepam solution over a few weeks, there may be a loss of effectiveness (due to the development of tolerance to the hypnotic effect of benzodiazepines).

Development of dependence

Diazepam solution is an addictive medicine (primary dependence potential). Diazepam solution may cause dependence, even at therapeutic dosages. The risk of dependence increases with dose and duration of treatment; it is also greater in patients with a history of alcohol or drug abuse. Therefore, you should use Diazepam solution for as short period of time as possible.

Discontinuation of therapy/withdrawal symptoms

Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. These may consist of

increased dreaming, sweating, trembling, headaches, muscle pain, extreme anxiety, mood swings, tension, restlessness, confusion and irritability.

In severe cases, the following symptoms may occur: impaired self-perception or perception of one's surroundings (derealization, depersonalization), confusional state, hypersensitivity to light, noise (hyperacusis) and physical contact, numbness and tingling of the extremities, hallucinations or epileptic seizures.

The symptoms that led to treatment with Diazepam solution may recur in an enhanced form on withdrawal of treatment. Since the risk of withdrawal phenomena is greater after abrupt discontinuation of treatment, it is recommended that the dosage is decreased gradually.

Memory disorder

Diazepam may cause short-term memory loss (anterograde amnesia) using therapeutic dosages. For example, this means that you may no longer be able to recall actions you carried out after using Diazepam solution. The condition occurs often several hours after administration of the medicinal product. This risk increases with the dosage level and can be reduced by a sufficiently long, uninterrupted duration of sleep (7-8 hours).

Psychological and "paradoxical" reactions

Reverse effects such as restlessness, agitation, irritability, aggressive behaviour, nightmares, hallucinations, delusions, rages, inappropriate behaviour and other behavioural disorders or abnormal condition of the mind (psychosis), may occur when using benzodiazepines, especially in elderly patients or children (see section 4). In such cases, treatment with Diazepam solution should be discontinued.

Psychoses

Diazepam is not recommended for the primary treatment of mental and psychiatric disorders (psychotic illness).

Depression

Diazepam should not be used alone to treat depression or states of anxiety that occur in association with depression. In some circumstances, the clinical symptoms of depression may be aggravated (risk of suicide).

The application without medical advice by a doctor will reduce the opportunity that this medicine will help you. At the latest after four weeks of use, your doctor will decide whether your treatment should be continued. Do not increase in any case your prescribed dose, even if the effect ceases. The aimed treatment is complicated by arbitrary increase of dosage.

Do not use benzodiazepines because they help others so good.

Children and adolescents

Diazepam should only be given to children and adolescents if a doctor thinks this is necessary and any treatment should be kept to a minimum.

Elderly patients

Elderly should be given a reduced dose (see section 3). Caution is advised in elderly patients due to the risk of falling and consequently fractures, particularly when getting up at night (see section 4). Falling may occur because of the muscle relaxing effect of diazepam.

Specific patient groups

A lower dose is recommended for patients with chronic respiratory insufficiency due to the risk of respiratory depression. It is also recommended that debilitated patients and those with hepatic and renal impairment should receive a reduced dose and special caution is advisable (see section 3). Benzodiazepines are not indicated to treat patients with severely impaired liver function as they may precipitate brain disorder (encephalopathy).

High-risk patients

Benzodiazepines should be used with extreme caution in patients with a history of alcohol or drug abuse.

Other medicines and Diazepam solution

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines. This is especially important for the following medicines as they may interact with Diazepam solution:

- antipsychotics (treatments for mental illness)
- anxiolytics (treatments for anxiety)
- sedatives or hypnotics (e.g. sleeping pills)
- antidepressants (treatments for depression, such as fluvoxamine, fluoxetine)
- narcotic analgesics (strong painkillers)
- anaesthetics
- antiepileptics (treatments for epilepsy, e.g. phenytoin, phenobarbital)
- sedative antihistamines (treatments for allergies that make you sleepy)

- pain killers, e.g. buprenorphine
- azole antimycotics, used to treat fungal infections (itraconazole, ketoconazole, fluconazole, voriconazole)
- HIV protease inhibitors which are used to treat HIV infection
- isoniazid (for tuberculosis - TB)
- disulfiram (for treatment of alcoholism)
- cimetidine, omeprazole (drugs for heartburn and ulcers)
- oral contraceptives (e.g. 'The Pill')
- muscle relaxants
- rifampicin (an antibiotic)
- theophylline (tablets for asthma)
- levodopa (for Parkinson's disease)
- sodium oxybate (used to treat narcolepsy)
- St. John's wort (used to treat depression)

Concomitant use of Diazepam solution 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 Diazepam solution 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.

Nicotine (e.g. smoking) may reduce the efficacy (effectiveness) of Diazepam solution.

It may still be all right for you to be given Diazepam and your doctor will be able to decide what is suitable for you.

Diazepam solution with alcohol

Do not drink alcohol while you are using Diazepam. Alcohol may increase the sedative effects of Diazepam and make you very sleepy.

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.

Pregnancy

You should not use this medicine if you are pregnant unless your doctor tells you to use it. Tell your doctor straight away if you think you may be pregnant.

There may be a slight increase in abnormalities, particularly hare lip, in babies born to mothers given benzodiazepines during pregnancy. Babies exposed to overdoses of benzodiazepines during pregnancy may be slow developers, may have eye movement disorders (nystagmus) or congenital abnormalities. If you use Diazepam during pregnancy over a longer period or in high doses, your newborn may suffer from withdrawal symptoms. If you have received Diazepam towards the end of pregnancy or during labour, the baby may be affected, with feeling cold, floppiness, difficulty breathing and poor suckling (so-called "floppy infant syndrome").

Breast-feeding

Do not use Diazepam during lactation because it enters the breast milk. For this reason, if Diazepam therapy is essential, breast-feeding should be terminated in order to avoid side effects in the breast-fed infant.

Driving and using machines

You must not drive or use machines until 24 hours after the last dose. After 24 hours, if you still feel sleepy or find it hard to concentrate, if you notice muscle weakness or episodes of memory loss you should not drive or operate machines and tell your doctor.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while using 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 using this medicine.

Diazepam solution contains propylene glycol, benzyl alcohol, benzoic acid and sodium benzoate

This medicine contains 37.5 mg benzyl alcohol in each rectal tube which is equivalent to 15 mg/ml. Benzyl alcohol may cause allergic reactions.

This medicine contains 2.5 mg benzoic acid (E210) and 122.5 mg sodium benzoate (E211) in each rectal tube which is equivalent to 1 mg benzoic acid per ml and 49 mg sodium benzoate per ml. Benzoic acid and sodium benzoate may cause local irritation.

This medicine contains 1 mg propylene glycol in each rectal tube which is equivalent to 400 mg/ml. Propylene glycol may cause skin irritation.

3. How to use Diazepam solution

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The usual dose is 0.25 - 0.5 mg/kg (body weight). The dose also depends on the patient's age and health. Diazepam is for use in adults and children (weighing more than 10 kg).

The recommended dose is:

- for children between 1 and 3 years (10-15kg): one 5 mg tube
- for children over 3 years (more than 15 kg): one 10 mg tube
- for adults: two 10 mg tubes

Your doctor will decide the appropriate dose and for how long you need to take this medicine. The usual duration of treatment is not longer than 4 weeks. If needed, your doctor might increase the duration of treatment.

Method and duration of administration

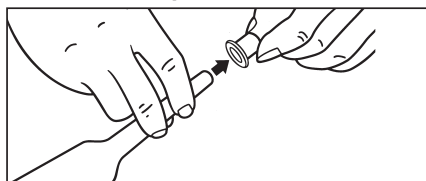
Diazepam solution is for use in emergency cases. It is not intended for long-term use. If it becomes necessary, the dose may be repeated every 12 hours. If convulsions (fits) are still not controlled the doctor should be contacted.

The tubes containing Diazepam solution are for rectal (into the anus) and single use only. Treatment should be as short as possible. The lowest dose that can control the symptoms should be used. If used continuously for too long, there is a risk of becoming dependent on diazepam or of having problems when stopping it.

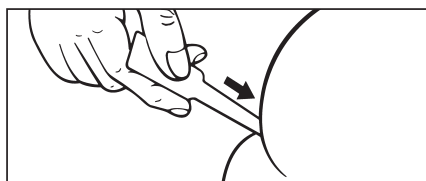
If no effect is seen after 10 minutes, the dose can be repeated in children or an additional 10 mg tube given to adults.

Elderly and debilitated patients or those with liver or kidney dysfunction or chronic breathing disorder may need a reduced dose.

How to use Diazepam solution

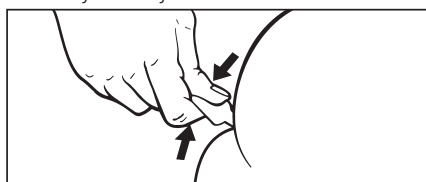


1. If possible, turn patient on side, or front for a child.
2. Tear open the foil back.
3. Remove the tube cap.



4. Insert the nozzle completely into the anus, pointing it downwards.

Note: In children under 15 kg insert the nozzle only half way.



5. Empty the tube by pressing firmly between the thumb and index finger.
6. Keep the tube **completely pressed together** until you have drawn it out of the rectum.

Note: A small amount of the solution is intended to be left in the tube after the dose has been given.

7. Keep the patient's position and hold the buttocks together for a few minutes to prevent leakage.

If you use more Diazepam solution than you should

If you have used more Diazepam solution than you should, talk to a doctor immediately.

Symptoms of overdose include drowsiness, sleepiness, mental confusion, lethargy (a drowsy dullness), speech disorders and involuntary eye movements (nystagmus).

If such signs of illness appear, a doctor must be told immediately, who will decide on their severity and any measures that may be required.

In serious cases, symptoms include low blood pressure, loss of reflexes, shallow breathing (respiratory and circulatory insufficiency, turning blue (cyanosis), loss of consciousness progressing to the development of respiratory and cardiac arrest), co-ordination problems (ataxia), floppiness, coma (rare) and death (very rare). In the phase of subsidence of intoxication, severe states of restlessness, insomnia and possibly major convulsions may occur.

The symptoms of overdose are increased under the influence of alcohol and other centrally depressant drugs.

If you stop using Diazepam solution

Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. Since the risk of withdrawal phenomena/rebound phenomena is greater after abrupt discontinuation of treatment, it is recommended that the dosage is decreased gradually.

Withdrawal symptoms include headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases, the following symptoms may occur: derealization (the world feels unreal), depersonalization (feeling detached from your body), hyperacusis (sensitivity to sound), numbness and tingling, sensitivity to light, voices or physical contact, hallucinations, epileptic fits, mood changes, anxiety or sleep disturbances and restlessness.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Common: may affect up to 1 in 10 people

- sedation, drowsiness, headaches, dizziness (with risk of falls in the elderly), unsteadiness, speech disorders such as slurred speech, trembling hands
- tiredness, hangover effect
- seeing double
- muscle weakness
- muscle cramps
- reduced alertness, numbed emotions, confusion and short-term memory disturbances (anterograde amnesia) which can be associated with inappropriate behaviour (see section 2)
- paradoxical reactions - instead of feeling sleepy, some patients (particularly children or the elderly) may feel agitated with a change in their personality. Other symptoms are restlessness, anxiety, changing mood, suicidal tendencies, aggressiveness, rage, irritability, tension, irrational ideas (delusions), nightmares, sleeplessness, hallucinations (sensing things that are not real), hostility or inappropriate behavior. If you experience any of these effects, contact your doctor.

Uncommon: may affect up to 1 in 100 people

- impaired concentration

Rare: may affect up to 1 in 1,000 people

- low blood pressure
- slow pulse, heart failure, including cardiac arrest
- chest pain
- blood cell changes, including reduced number of platelets
- eye changes including blurred vision and involuntary eye movements (nystagmus)
- dry mouth
- nausea (feeling sick), vomiting (being sick), epigastric pain (heartburn/indigestion), obstipation (severe constipation), diarrhoea
- jaundice (yellow skin)
- problems in passing water or involuntary urination
- increase or loss of sexual desire, problems with menstrual periods
- spasm of the airway, difficulty with breathing, temporary stopping of breathing (apnoea),

cessation of breathing (respiratory arrest). The respiratory-depressant effect may be more marked in cases of existing shortness of breath caused by constricted airways (respiratory tract obstruction) and in patients with brain damage. This should be borne in mind particularly if used at the same time as other centrally active medicines (see section 2).

- increased appetite
- hangover effects in the morning after evening administration which may lead to disturbance of concentration and tiredness and may impair reaction capacity
- changes of liver blood tests (increased transaminases and alkaline phosphatase)

Very rare: may affect up to 1 in 10,000 people

- skin rashes, including itching and hives
- swelling of face, mouth, tongue or other body parts that may cause breathing difficulties (angioedema)

Not known (frequency cannot be estimated from the available data):

- dizziness with disturbance of equilibrium (vertigo)
- increased salivation
- risk of falls (see section 2. "Elderly patients")

Diazepam solution may cause dependence, even at therapeutic dosages. Stopping treatment may cause withdrawal effects. In some patients, depression may occur.

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 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 Diazepam solution

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 package. The expiry date refers to the last day of that month.

Do not store above 25°C. Short-term exposure to higher temperatures (e.g. in the car or emergency bag) is possible and does not affect the quality of the medicine.

Do not throw away any medicines via wastewater. 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 Diazepam solution contains

- The active substance is diazepam.
- The other ingredients are: benzyl alcohol, ethanol 96%, propylene glycol, benzoic acid, sodium benzoate and purified water

What Diazepam solution looks like and contents of the pack

Diazepam solution is a clear, colourless or slightly yellowish solution in a white polyethylene tube.

Pack of 5 rectal tubes. Each tube contains 2.5 ml solution of diazepam 5 mg or 10 mg.

Marketing Authorisation Holder and Manufacturer

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