

Diazepam 4mg/ml – 2,5ml Rectal Solution Tubes

Uses

Diazepam belongs to a group of medicines known as benzodiazepines. Diazepam has anticonvulsant, sedative, and muscle relaxant properties. It is used in the treatment of severe anxiety and tension states, as a sedative and premedication, in the control of muscle spasm, or other circumstances in which a rapid effect is required but where intravenous injection is impracticable or undesirable.

Dose and method of administration

Always use this medicine exactly as your doctor or pharmacist has told you.

Diazepam rectal solution should not be given to children and adolescents under 18 years of age, unless it is determined necessary by a doctor.

The usual dose is 0.25 - 0.5 mg/kg body weight, but the prescribed dose varies depending on the age and health of the patient.

The recommended dose for adults is two rectal tubes of 10 mg. Elderly patients should receive a lower dose.

The solution is administered rectally. The patient should lie down on the side.

- Tear open the foil pack. Remove the cap.

- Insert the tube nozzle completely into the rectum. Hold the tube with the spout downwards. The contents of the tube should be completely emptied by using firm pressure with the index finger and thumb.

- To avoid suction, maintain pressure on the tube until it is withdrawn from the rectum. Press the patient's buttocks together for a short time.

Contraindications

Do not use this medicine in case of: • hypersensitivity to diazepam, benzodiazepines or to any of the excipients • phobic or obsessional states, chronic psychosis, hyperkinesia • severe breathing problems • myasthenia gravis • sleep apnoea • severe liver disease • acute porphyria • pregnancy • as monotherapy in patients with depression or those with anxiety and depression, as suicide may be precipitated in such patients.

Special warnings and precautions for use

Talk to your doctor or pharmacist before using diazepam rectal solution if: • you have kidney or liver disease • you have difficulty breathing • you have poor blood supply to the brain or any kind of brain damage • you have a history of alcohol or drug abuse.

Diazepam solution should not be taken simultaneously with alcohol and/or drugs with a depressant effect on the central nervous system.

Diazepam solution can cause dependence even at therapeutic doses. 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 the diazepam solution for the shortest time possible.

Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. Since the risk of withdrawal symptoms is greater after abrupt cessation of treatment, it is recommended that the dose be reduced gradually.

Interactions

Before taking diazepam rectal solution, inform your doctor or pharmacist about all the other medicines that you are taking or have recently taken, especially: • antipsychotics • anti-anxiety drugs • tranquilizers or sleeping pills • antidepressants for severe depression (such as fluvoxamine, fluoxetine) • narcotic analgesics • anaesthetics • anticonvulsants • sedative antihistamines • painkillers e.g. buprenorphine •azole antifungals (such as itraconazole, ketoconazole, fluconazole, voriconazole) • HIV protease inhibitors • isoniazid • disulfiram • cimetidine, omeprazole • oral contraceptives • muscle relaxants • rifampicin • theophylline • levodopa • sodium oxybate • St. John's wort • opioids.

Nicotine may reduce the effectiveness of diazepam solution. Alcohol can increase the sedative effect of diazepam.

Undesirable side effects

Tell your doctor immediately if you experience signs of a rare but serious allergic reaction: sudden difficulty breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Other possible side effects:

Common: • sedation, somnolence • headache • dizziness, unsteadiness • speech disorders such as slurred speech • hand tremors • fatigue • double vision • muscle weakness • muscle cramps • decreased alertness • numbed emotions • confusion • transient memory impairment • paradoxical reactions - instead of feeling drowsy, some patients (especially children or the elderly) may feel agitated • restlessness, anxiety • mood swings • suicidal tendencies • aggressiveness, anger, irritability • delusions • nightmares • insomnia • hallucinations.

Rare: • slow heartbeat • heart failure • chest pain • blood cell changes, including a decreased number of platelets • eye changes including blurred vision and involuntary eye movements • dry mouth • nausea • vomiting • epigastric pain • constipation • diarrhea • jaundice • difficulty urinating or involuntary urination • increase or loss of sexual desire • menstrual problems • spasm of the airways, difficulty breathing.

If you get any side effects, talk to your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet.

Effects on ability to drive and use machines

You should not drive or use machines while being treated with diazepam rectal solution and for 24 hours after the last administration. If after 24 hours you still feel sleepy or find it difficult to concentrate, or have episodes of memory loss, do not drive or use machines and contact your doctor.

Pregnancy and lactation

If you are pregnant, breast-feeding or planning to become pregnant, talk to your doctor before taking diazepam rectal solution. This medicine is not recommended for use in pregnant or breast-feeding patients.

Overdose

Contact a doctor or hospital immediately if you have used too much of this medicine. The symptoms of an overdose include ataxia, drowsiness, dysarthria, sedation, muscle weakness, increased sleepiness, hypotension, bradycardia, involuntary eye movements or paradoxical excitation.

How to store

Store away from heat and direct sunlight, below 25°C. Keep out of reach of children. Do not use after the expiry date.