Diazepam 5mg/10mg rectal solution

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 taking this medicine:
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Diazepam is and what it is used for
2. Before you use Diazepam
3. How you use Diazepam
4. Possible side effects
5. How to store Diazepam
6. Further information

1. WHAT DIAZEPAM 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. BEFORE YOU USE DIAZEPAM
Do not use Diazepam solution if:
- you are allergic (hypersensitive) to diazepam or any of the other ingredients of Diazepam solution (see list of ingredients in Section 6). An allergic reaction may include rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue.
- you have myasthenia gravis (very weak muscles)
- you suffer from sleep apnoea (temporary stopping of breathing during sleep)
- you have a severe liver disorder
- you have a severe breathing disorder
- Diazepam should not be used for premature babies

Take special care with Diazepam solution (and talk to your doctor) if you:
- have a kidney or liver disorder
- have a breathing disorder
- have glaucoma (high pressure in the eye)
- have a poor blood supply to the brain or any brain damage
- have a history of alcohol or drug abuse
- are suffering from mental illness

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

Withdrawal symptoms
The dependence potential of diazepam is low when limited to short-term use. However, withdrawal symptoms might be experienced including 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.

Reducing the dose gradually can help prevent any withdrawal effects. Diazepam solution may not be as effective after repeated use for a few weeks.

Taking other medicines
Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. This is especially important of 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)
- antiepileptics (treatments for epilepsy, e.g. phenytoin)
- anaesthetics
- antiepileptics (treatments for epilepsy, e.g. phenytoin)
- antihistamines (treatments for allergies that make you sleepy)
- antidepressants (treatments for depression)
- sedative antihistamines (treatments for allergies that make you sleepy)
- anxiolytics (treatments for anxiety)
- antipsychotics (treatments for mental illness)
- anxiolytics (treatments for anxiety)
- sedatives or hypnotics (e.g. sleeping pills)
- antiepileptics (treatments for epilepsy, e.g. phenytoin)
- antihistamines (treatments for allergies that make you sleepy)

There may be a risk of increased sedation when taking diazepam with:
- anxiolytics (treatments for anxiety)
- sedatives or hypnotics (e.g. sleeping pills)
- antiepileptics (treatments for epilepsy, e.g. phenytoin)
- antipsychotics (treatments for mental illness)
- anxiolytics (treatments for anxiety)
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- antipsychotics (treatments for mental illness)
- antihistamines (treatments for allergies that make you sleepy)

Driving and using machines
You should 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.

Important information about some of the ingredients of Diazepam solution
Diazepam solution contains Benzoic acid (E210) and sodium benzoate (E211). These may irritate the skin, eyes, nose and throat and may also increase the risk of jaundice (yellow skin) in newborn babies.

3. HOW YOU USE DIAZEPAM RECTAL SOLUTION

Dosage
Always use Diazepam solution exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is 0.25 – 0.5mg/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 10kg).

The recommended dose would be normally:
- for children between 1 and 3 years (10 – 15kg): one 5mg tube
- for children over 3 years (more than 15kg): one 10mg tube
- for adults: two 10mg tubes

Diazepam solution is for use in emergency cases. They are 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 10mg tube given to adults.

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

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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 15kg 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 take more Diazepam solution than you should

If you have taken more Diazepam solution than you should, talk to a doctor or pharmacist immediately.

Symptoms of overdose include drowsiness, mental confusion and lethargy (a drowsy dullness).
In serious cases, symptoms include low blood pressure, shallow breathing, co-ordination problems, floppiness, coma (rare) and death (very rare).

If you stop taking Diazepam solution

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 about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diazepam solution 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 (between 1 and 10 patients out of 100): Sedation, drowsiness, headaches, dizziness (with risk of falls in the elderly), unsteadiness, slurred speech, trembling hands, tiredness, hangover effect, seeing double, muscle weakness, reduced alertness, numbed emotions, confusion, and forgetfulness.

Also common are 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, changing mood, rage, delusions (irrational ideas), nightmares or hallucinations (sensing things that are not real).

Rare (between 1 and 10 patients out of 10000):
Low blood pressure, slow pulse, chest pain, blood cell changes, eye changes, Dry mouth, Nausea (feeling sick), vomiting (being sick), epigastric pain (heartburn/indigestion), obstipation (severe constipation), diarrhoea, jaundice (yellow skin), problems in passing water, changes in sexual desire, problems with periods, spasm of the airway, difficulty with breathing, apnoea (temporary stopping of breathing), increased appetite.

Very rare (less than 1 patient out of 10000): Skin rashes.

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE

DIAZEPAM RECTAL SOLUTION

Diazepam solution should be kept out of the reach and sight of children.
Store below 25°C. Do not use after the expiry date stated on the package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

6. FURTHER 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 Rectal Solution is a clear, colourless or slightly yellowish solution in a white polythene tube.
Pack of 5 rectal tubes. Each tube contains 2.5ml solution of diazepam 5mg or 10mg.

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