Diazepam 2mg/5ml Oral Solution Sugar Free PIL - UK

Item number: BBBA2034

**Technical Approval**

- **Date sent:** 18.05.18
- **Date received:** 22.05.18

**Colours**

1. Black
2. 3.
4. 5.
6.

**Non Printing Colours**

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**Dimensions:** 210 x 148

**Supplier:** Pinewood Labs

**Min Body Text Size:** 7pt

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**Diazepam 2mg/5ml Oral Solution Sugar Free**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Do not take if allergic to diazepam, benzodiazepines, medicines obtained without a prescription, or to any of the other ingredients of this medicine.
- Certain medicines may affect the way this medicine works, or this medicine may affect the way other medicines work.
- Diazepam can be weakened.

**1. What is Diazepam oral solution and what it is used for**

Diazepam belongs to a group of medicines called benzodiazepines. Diazepam helps in the treatment of anxiety; muscle spasms and convulsions (fits). It is used to treat:

- **In adults**:
  - short-term relief (14 days) of severe anxiety which may occur alone or with insomnia (treatment of anxiety; muscle spasms and convulsions (fits). It is used to treat):
  - cerebral palsy
  - epilepsy (when taken with other medicines)
  - myasthenia gravis
  - suffering from or have a condition which may cause diazepam to be removed from the body more slowly than usual and therefore increase the risk of side effects, such as making you feel sleepy or longer cause difficulty breathing. Taking these medicines with diazepam can affect your mental state, make you very sleepy and suppress your breathing and blood pressure.
  - disulfiram (to treat alcohol addiction). Taking this medicine with alcohol could make you very sleepy and can cause diazepam to be removed from the body more slowly than usual.
  - medicines for epilepsy (e.g. phenobarbital, phenytoin and carbamazepine, sodium valproate, diazepam can affect the blood levels of these medicines). Diazepam can further affect how certain medicines work:
  - theophylline (to treat asthma and other breathing disorders), as it can weaken the effect of diazepam.
  - succinylcholine (used to treat tuberculosis), as it can cause diazepam to be removed from the body more slowly than usual.
  - corticosteroids (medicines to treat inflammation in the body) as they can weaken the effect of diazepam.
  - levodopa (to treat Parkinson's disease).
  - valproic acid (used to treat epilepsy and mental disorders) as it can slow down the removal of diazepam from the body and increase its effect.
  - ketamine (an anaesthetic) as diazepam increases the effect of ketamine.
  - loxiflavin (to help relieve symptoms when you stop taking opioids)
  - nabilone (to treat nausea and vomiting)
  - alpha blockers or moraxine (to lower high blood pressure)

**Pregnancy and breast-feeding**

- if you are pregnant, your baby may develop withdrawal symptoms. Ask your doctor or pharmacist for advice before taking this medicine.

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**Please note that only Artwork Studio is permitted to make changes to the above artwork.**

No changes are permitted by any 3rd party other than added notes and mark ups for required changes.
Driving and using machines
Diazepam oral solution can make you sleepy, forgetful, have poor co-ordination along with other side effects that can affect everyday activities (see section 4). You should not drive, operate machinery or take part in such activities where, if affected, you could put yourself or others at risk.

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.
- 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.

Diazepam oral solution contains sorbitol, Propyl parahydroxybenzoate (E216), Methyl parahydroxybenzoate (E218) and glycerol Diazepam oral solution contains 1.91g to 2.55g of sorbitol per 5ml solution. This may have a mild laxative effect. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine. Caloric value: 2.6 kcal/g sorbitol

Diazepam oral solution contains 2.50g of Propyl parahydroxybenzoate (E216) per 5ml solution and 5.000g of Methyl parahydroxybenzoate (E218) per 5ml solution. May cause allergic reactions (possibly delayed).

Diazepam oral solution contains 0.63g of glycerol per 5ml solution. May cause headache, stomach upset and diarrhoea in doses higher than 3mg.

3. How to take Diazepam oral solution
Always take this medicine exactly as your doctor has told you. You should not take Diazepam oral solution for longer than 4 weeks. Check with your doctor or pharmacist if you are not sure. You should make sure you are able to have 7-8 hours of uninterrupted sleep.

The recommended dose is:
- Adults
  • Anxiety or mental health problems: 2mg-30mg each day, in divided doses
  • Insomnia: 5mg-30mg at bedtime
  • Cerebral palsy: 2mg-60mg each day, in divided doses
  • Other spasms: 5mg-60mg each day, in divided doses
  • Status epilepticus: 2mg-1mg each day, in divided doses
  • Epilepsy as a premedication: 2mg-60mg per day, in divided doses
  • Epilepsy: 5mg-20mg daily
  • Alcohol withdrawal symptoms: 5mg-20mg which may be repeated after 2 to 4 hours if necessary.
  • Before dental treatment: 5mg the night before treatment, 5mg on waking and 5mg two hours before the appointment

Children and adolescents
- Cerebral spasms: 2mg-40mg each day, in divided doses
- For muscle spasm associated with tetanus, the adult dose is usually given in divided doses.

Epilepsy: 2mg-10mg daily

Specific patient groups
- Elderly or frail
  you are likely to be more sensitive to the effects of Diazepam oral solution, especially sedation, drowsiness and confusion.
- Your doctor will give you much lower doses, this should not be more than half the adult dose.
- Breathing difficulties: you may be given a lower dose.
- If you take more Diazepam oral solution than you should
  If you (or someone else) swallow a lot of Diazepam Oral Solution, or you think a child or teenager may have taken it, take them to the nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include loss of coordination of muscle movements (these side effects disappear after a few hours). Diazepam oral solution work) is diazepam. Each 5ml contains: 0.63g of glycerol, raspberry flavour, saccharin sodium, aluminium magnesium silicate, propylene glycol, raspberry flavour. Each 5ml contains: 0.63g of glycerol, raspberry flavour, saccharin sodium, aluminium magnesium silicate, propylene glycol, raspberry flavour.

4. Possible Side Effects
Like all medicines, this medicine can cause side-effects, although not everybody gets them. Stop treatment and contact a doctor at once if you have:
- Allergic reaction (itchy skin, rash, sudden swelling of the face, lips, tongue, throat, or body, rash, fainting or difficulty breathing or swallowing)
- Respiratory depression (very slow and/or shallow breathing) (Uncommon)
- Respiratory arrest (cessation of breathing) (Rare)

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
- Common: may affect more than 1 in 10 people
  • Drowsiness
  • Common: may affect up to 1 in 10 people
  • Fatigue
  • Withdrawal symptoms (for possible symptoms please see ‘If you stop taking Diazepam oral solution’ in Section 3)
  • Confusion
  • Loss of coordination of muscle movements (ataxia) and other movement disorders, tremor
  • Uncommon: may affect up to 1 in 100 people
  • Memory loss
  • Difficulty in concentrating
  • Balance disorders
  • Dizziness
  • Headache
  • Speech problems
  • Irregular or slow breathing
  • Increased blood pressure

Report 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 Diazepam oral solution
Keep out of the sight and reach of children. Do not store above 25°C. Keep container in the outer carton and keep the container tightly closed. Do not use Diazepam oral solution after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
What Diazepam oral solution contains
- The active substance (the ingredient that makes the oral solution work) is diazepam. Each 5ml contains: 0.63g of the active ingredient.
- The other ingredients are: sucrose, sodium, magnesium, silicon, propylene glycol, raspberry flavour, saccharin sodium, perl zinc, propyl parahydroxybenzoate (E216), methyl parahydroxybenzoate (E218), sorbitol (E420), glycerol (E422).

What Diazepam oral solution looks like and contents of the pack
Diazepam oral solution is a pink syrup with an odour of raspberries.
Pack sizes are 100ml.

Marketing Authorisation Holder and manufacturer:
Actavis, Barnstable, EX32 8NS, UK
This leaflet was last revised in May 2018

Diazepam 2mg/5ml Oral Solution Sugar Free PIL - UK

Item number: BBBA2034

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Dimensions: 210 x 148

Colours

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FMD info

NA (not a carton) Yes

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Version 2
01.11.2017