

Package leaflet: Information for the user

Diazemuls Emulsion for Injection

5 mg/ml

diazepam

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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1 What Diazemuls is and what it is used for

2 What you need to know before you take Diazemuls

3 How to take Diazemuls

4 Possible side effects

5 How to store Diazemuls

6 Contents of the pack and other information

1 What Diazemuls is and what it is used for

Diazemuls contains diazepam which belongs to a group of medicines called benzodiazepines.

Diazemuls is used

- as a premedication in minor surgery
- in the treatment of convulsions e.g. epilepsy
- to control muscle spasm including that associated with tetanus
- in the treatment of severe acute anxiety or agitation, including alcohol withdrawal symptoms (delirium tremens)

2 What you need to know before you take Diazemuls

Do not take Diazemuls if you:

- are **allergic** to diazepam, to other benzodiazepine or to any of the other ingredients of this medicine (listed in section 6)
- have **severe liver** disorders
- suffer from **sleep apnoea syndrome** (a sleep disorder where you have abnormal pauses in breathing during sleep)
- have **acute respiratory depression** (slow and/or shallow breathing)
- suffer from **myasthenia gravis** (a condition which causes muscle weakness)

If any of the above points apply to you, or if you are not sure, tell the doctor before you are given Diazemuls.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diazemuls if you:

- are **elderly** or if you suffer from **chronic lung problems**, you should be given a reduced dose of Diazemuls.
- have an **alcohol or drug problem**, you should tell the doctor before you are given Diazemuls.
- suffer from a **psychotic illness, depression, or anxiety related to depression** you should not be treated with Diazemuls alone.
- have **epilepsy** or a history of **seizures**.
- have **suicidal thoughts**.

- **Mental side effects** – contact your doctor if you experience side effects such as agitation, hyperactivity, restlessness, aggressiveness, nightmares or hallucinations. These side effects are more likely to occur in children or the elderly (see section 4).

- **Amnesia** – you could experience amnesia when taking this medicine. Amnesia is more likely to occur when taking high doses of diazepam.

- **Dependence** – when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take Diazemuls for as short period of time as possible.

- **Tolerance** – if after a few weeks you notice that this medicine is not working as well as it did when first starting treatment, you should speak to your doctor.

- **Withdrawal** – treatment should be gradually withdrawn. Withdrawal symptoms occur with Diazemuls even when normal doses are given for short periods of time. See Section 3, ‘If you stop taking Diazemuls’.

Other medicines and Diazemuls

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- **antipsychotics** such as clozapine (to treat mental problems)
- **hypnotics** (to help you sleep)
- **antihistamines** (to treat allergies)
- **antidepressants** (e.g. fluvoxamine, fluoxetine)
- **sedatives** (used to give calming effects)
- **general anaesthetics**
- **muscle relaxants** (e.g. suxamethonium, tubocurarin)
- **strong analgesics** (drugs used to treat severe pain) such as morphine (opioids)
- barbiturates such as **phenobarbital** (to treat epilepsy and mental disorders)

Taking these medicines with Diazemuls could affect your mental status, make you very sleepy and suppress your breathing and blood pressure.

- **anti-epileptics** (phenytoin and carbamazepine), as these can reduce the effect of Diazemuls. Furthermore, Diazemuls can affect how phenytoin works.

- **cimetidine, omeprazole or esomeprazole** (medicines used to reduce acid in your stomach), as these can cause Diazemuls to be removed from the body more slowly than usual.

- **anti-viral agents** (e.g. atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir or saquinavir) and **anti-fungal agents** (e.g. fluconazole, itraconazole, ketoconazole or voriconazole) as these medicines can cause Diazemuls to be removed from the body more slowly than usual and therefore increase the risk of side effects.
- **rifampicin** (an antibiotic) as this medicine can cause Diazemuls to be removed from the body more quickly than usual. The effect of Diazemuls can be weakened.
- **theophylline** (to treat asthma and other breathing disorders), as it can weaken the effect of Diazemuls.
- **disulfiram** (to treat alcohol addiction). Taking this medicine with Diazemuls could make you very sleepy and can cause Diazemuls to be removed from the body more slowly than usual.
- **isoniazid** (used to treat tuberculosis), as it can cause Diazemuls to be removed from the body more slowly than usual.
- **oral contraceptives**, as they can slow down the removal of Diazemuls from the body and increase its effect. Breakthrough bleeding can occur when taking Diazemuls and oral contraceptives together, but the contraceptive protection is not reduced.
- **cisapride** (used to treat stomach problems), as it can cause Diazemuls to be removed from the body more slowly than usual.
- **corticosteroids** (medicines used to treat inflammation in the body) as they can weaken the effect of Diazemuls.
- **levodopa** (used to treat Parkinson's disease). Diazemuls can reduce the effect of levodopa.
- **valproic acid** (used to treat epilepsy and mental disorders) as it can slow down the removal of Diazemuls from the body and increase its effect.
- **ketamine** (an anaesthetic) as Diazemuls increases the effect of ketamine.
 - Concomitant use of Diazemuls 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 <Product name> 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.

Diazemuls with food, drink and alcohol

It is recommended not to drink alcohol while you are using Diazemuls. Alcohol may increase the sedative effects of Diazemuls and make you very sleepy.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Diazemuls **must not be used** if you are pregnant or might become pregnant. If your doctor has decided you should receive Diazemuls during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing difficulties. If Diazemuls is used regularly in late pregnancy, your baby might develop withdrawal symptoms.

Diazemuls **must not be used** if you are breast-feeding as diazepam enters breast milk and may affect the baby.

There are no data on the effects of Diazemuls on fertility in humans.

Driving and using machines

Diazemuls may make you feel sleepy and affect your concentration. It may also affect how your muscles work. You **should not** drive or operate machinery if you are affected this way.

The effects of Diazemuls may continue for several days after discontinuation of the product.

Diazemuls contains egg phospholipids and soya bean oil

If you are allergic to eggs, soya beans or peanuts, do not use this medicinal product.

3 How to take Diazemuls

Diazemuls may be administered by a doctor or a nurse as an intramuscular injection, as a slow intravenous injection, or as a continuous infusion (min. 4 ml per hour).

Diazemuls should not be given to children without careful assessment.

The recommended doses are:

- **severe anxiety or agitation including symptoms of alcohol withdrawal:** 10 mg repeated at intervals of 4 hours as required
- **acute muscle spasm including that associated with tetanus:** 0.1-0.3 mg per kg of body weight by intravenous injection repeated every 1-4 hours as required, or a continuous infusion of 3-10 mg per kg of body weight every 24 hours
- **epilepsy:** initial dose of 0.15-0.25 mg per kg of body weight by intravenous injection repeated in 30 to 60 minutes if required, and followed if needed by infusion up to 3 mg per kg of body weight over 24 hours
- **convulsions:** adults: 10-20 mg intravenous or intramuscular injection
children: 0.2-0.3 mg/kg intravenous or intramuscular injection
- **premedication:** 0.1-0.2 mg per kg of body weight by intravenous injection, should be adjusted to the patient's response

If you are elderly or debilitated you are likely to be more sensitive to diazepam. Therefore, your dose may be reduced to one half the normal dose at the start of treatment.

The duration of treatment should be as short as possible, however where treatment continues for a number of weeks your doctor will evaluate your condition after a period of 4 weeks. In general treatment should not last longer than 8-12 weeks.

If you take more Diazemuls than you should

If you think you have had too much Diazemuls, contact your nearest hospital casualty department or tell your doctor immediately.

In mild cases signs of an overdose include drowsiness, mental confusion and lethargy. In more severe cases signs of an overdose may include loss of co-ordination of movements, low blood pressure, respiratory depression, and rarely, coma and death.

If you forget to take Diazemuls

If you think you have missed a dose, let your nurse or doctor know.

If you stop taking Diazemuls

Do not stop using your medicine without telling your doctor as he may wish to gradually reduce the number of injections you use before stopping them completely. If you stop using Diazemuls suddenly, you may experience unpleasant side effects, including headaches, muscle pain, anxiety, tension, restlessness, confusion and irritability.

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.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Some side effects can be serious and may require immediate medical attention:

Uncommon (affects 1 to 10 users in 1,000)

- Respiratory depression (very slow and/or shallow breathing)

Rare (affects 1 to 10 users in 10,000)

- Respiratory arrest (cessation of breathing)
- Unconsciousness
- Jaundice (yellowing of your skin or the white of your eyes)

Very rare (affect less than 1 user in 10,000)

- Anaphylaxis (severe allergic reaction) with symptoms such as sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow

Other side effects:

Very common (affects more than 1 user in 10)

- Drowsiness

Common (affects 1 to 10 users in 100)

- Confusion
- Uncoordinated muscle movements (ataxia), tremor, impaired movements
- Fatigue
- Withdrawal symptoms (for possible symptoms see section 3 'If you stop taking Diazemuls')

- Pain at the site of injection

Uncommon (affects 1 to 10 users in 1,000)

- Memory impairment, concentration difficulties, balance disorders, dizziness, headache, slurred speech
- Nausea, vomiting, constipation, diarrhoea, increased salivary secretion
- Allergic skin reactions such as itching, skin redness and swelling and skin rash
- Muscle weakness

Rare (affects 1 to 10 users in 10,000)

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, hallucinations, memory loss, delusion, rages, psychoses and nightmares. Decreased alertness, depression. May be or become serious. These side effects are more likely to occur in children or the elderly.
- Insomnia (problems sleeping)
- Heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest)
- Low blood pressure, fainting (syncope)
- Increased mucus in the lungs
- Dry mouth
- Increased appetite
- Changes in certain liver enzymes as seen in blood tests
- Lack of ability to urinate, loss of bladder control (incontinence)
- Abnormal breast enlargement in males (gynaecomastia)
- Inability to have an erection (impotence), changes in sexual drive (libido)

Very rare (affect less than 1 user in 10,000)

- Low levels of white blood cells (leukopenia)
- High levels of certain enzyme in the blood (transaminases)

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

- Reversible disorders of vision such as blurred vision, double vision (diplopia) and involuntary eye movements (nystagmus)

Use of Diazemuls may lead to the development of physical or psychic dependence.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Diazemuls

Keep this medicine out of the sight and reach of children. Store below 25°C. **Do not freeze.**

Keep the ampoule in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the ampoule label and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicine 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 Diazemuls contains

- The active substance is diazepam. 1 ml of the emulsion for injection contains 5 mg diazepam. Each 2 ml ampoule contains 10 mg of diazepam (therefore 10 mg/2 ml is the total quantity/volume).
- The other ingredients are soya bean oil, diacetylated monoglycerides, purified egg phospholipids, glycerol, sodium hydroxide, and water for injections.

What Diazemuls looks like and contents of the pack

Diazemuls is a white, milky fluid. Do not use if the product does not match this description. Pack sizes are in boxes of 10 x 2 ml ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

Manufacturer

Merckle GmbH
Graf-Arco-Str. 3
89079 Ulm
Germany

Actavis Group PTC ehf
Reykjavíkurvegur 76-78
IS-220 Hafnarfjörður
Iceland

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