

**Logo accord**

## **Package leaflet: Information for the patient**

### **Diazepam Accord 5mg/ml Emulsion for Injection**

**Read all of this leaflet carefully before you start receiving 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- This medicine contains diazepam, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly. If this medicine is being used for the treatment of epilepsy you must continue to take this medicine as instructed by your doctor.

#### **What is in this leaflet:**

- 1. What Diazepam is and what it is used for**
- 2. What you need to know before you are given Diazepam**
- 3. How to use Diazepam**
- 4. Possible side effects**
- 5. How to store Diazepam**
- 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 called benzodiazepines. This medicine has been prescribed to you and should not be given to anyone else.

Diazepam is used to treat a number of conditions, including:

- severe anxiety (which is an emotional state where you may sweat, tremble, feel anxious and have a fast heartbeat) or agitation
- muscle spasm due to tetanus or poisoning
- epilepsy
- patients with the symptoms of alcohol withdrawal
- helping relax patients before minor operations or procedures
- as a premedication before a general anaesthetic.

Benzodiazepines can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is

usually done gradually over a period which is specific to you and may occur over a period of weeks to months. If this medicine is being used for the treatment of epilepsy you must continue to take it as prescribed by your doctor.

## 2. What you need to know before you are given Diazepam

### Do not use Diazepam:

- if you are **allergic** to diazepam, to other benzodiazepine medicines or any of the other ingredients in this medicine (listed in section 6). This includes eggs, peanut or soya
- if you have a **phobia** (a fear of a particular object or situation), obsessions or other mental illness
- if you have **acute respiratory depression** (slow and/or shallow breathing)
- as the only treatment for **depression** (with or without anxiety)
- if you suffer from **hyperactivity**
- if you have a condition called **myasthenia gravis** which causes muscles to weaken and tire easily
- if you suffer from **sleep apnoea** (a sleep disorder where you have abnormal pauses in breathing during sleep)
- if you have **severe liver** disorders
- if you have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- if you are planning a **pregnancy** or are **pregnant** (see below Pregnancy and breast-feeding).

### Warnings and precautions

Talk to your **doctor, nurse or pharmacist** before being given Diazepam if you:

- suffer from **depression** (with or without anxiety)
- have problems with your **liver, kidneys or lungs**
- have someone **close to you** who has recently died
- have a **personality disorder**
- are **elderly**. Diazepam can cause confusion and have effects on muscles causing falls and injuries
- have **breathing problems**
- have **suicidal thoughts**
- have **epilepsy** or a history of **seizures**
- are or have ever been **addicted** to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake
- have previously suffered from **withdrawal** symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- feel you need to take more Diazepam to get the same level of symptom control, this may mean you are developing **tolerance** to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms. See section 3 “If you stop being given Diazepam”.

Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else.

Taking higher doses or more frequent doses of benzodiazepines, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

### **Children**

Diazepam should not be given to children under 6 months old.

### **Other considerations**

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

### **Other medicines and Diazepam**

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

- **antidepressants** (e.g. fluvoxamine, fluoxetine)
- **antipsychotics** such as clozapine (to treat mental problems)
- **antihistamines** (to treat allergies)
- **general anaesthetics**
- **sedatives** (used to give calming effects)
- **sodium oxybate** (to treat narcolepsy)
- **hypnotics** (to help you sleep)
- **erythromycin** (an antibiotic)
- **St Johns Wort**
- **hydralazine**
- **muscle relaxants** (e.g. suxamethonium, tubocurarin, baclofen, tizanidine)
- concomitant use of Diazepam 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 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. You may experience a heightened sense of wellbeing when opioids are taken with diazepam, which can increase your desire to continue taking these medicines (dependency) or can make you very sleepy

- barbiturates such as **phenobarbital** (to treat epilepsy and mental disorders)
- **medicines to lower high blood pressure, diuretics** (water tablets), **nitrates** (for heart conditions) as these could lower your blood pressure too much.

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

- **disulfiram** (to treat alcohol addiction). Taking this medicine with diazepam 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 furthermore affect how phenytoin works
- **theophylline** (to treat asthma and other breathing disorders) can weaken the effect of diazepam, as this can cause diazepam to be removed from the body more quickly than usual
- **cimetidine, omeprazole or esomeprazole** (stomach acid reducing medicines), as these can cause diazepam to be removed from the body more slowly than usual
- **rifampicin**, to treat infections (an antibiotic) as this can cause diazepam to be removed from the body more quickly than usual. The effect of diazepam can be weakened
- **zidovudine, amrenavir, atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir or saquinavir** (antivirals), **fluconazole, itraconazole, ketoconazole or voriconazole** (anti-fungal medicines) as these can cause diazepam to be removed from the body more slowly than usual and therefore increase the risk of side effects. These can make you feel sleepy for longer or cause difficulty breathing
- **isoniazid** (used to treat tuberculosis), as it can cause diazepam to be removed from the body more slowly than usual
- **oral contraceptives**, as they can slow down the removal of diazepam from the body and increase its effect. Breakthrough bleeding can occur when taking diazepam and oral contraceptives together, but the contraceptive protection is not reduced
- **cisapride** (used to treat stomach problems), as it can cause diazepam 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 diazepam

- **levodopa** (used to treat Parkinson's disease). Diazepam can reduce the effect of levodopa
- **ketamine** (an anaesthetic) as diazepam increases the effect of ketamine
- **lofexidine** (to help relieve symptoms when you stop taking opioids)
- **nabilone** (to treat nausea and vomiting)
- **alpha blockers** or **moxonidine** (to lower high blood pressure).

### **Diazepam with food and drink**

**Do not** drink alcohol if you are being given Diazepam. Alcohol may increase the sedative effects of Diazepam and make you very sleepy.

Grapefruit juice may increase the amount of diazepam in your blood. If you are elderly, suffer from cirrhosis or any of the conditions listed in section 2, this could possibly increase the sedative effects of Diazepam and you should speak to your doctor, nurse or pharmacist.

Drinks containing caffeine may reduce the effects of diazepam.

### **Pregnancy and breast-feeding**

You **should not** be given Diazepam if you are pregnant, planning to become pregnant or are breast-feeding. If you are given Diazepam late in your pregnancy or during labour your baby might have a low body temperature, floppiness, and breathing difficulties. If used regularly during late pregnancy, your baby may develop withdrawal symptoms. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this medicine.

### **Driving and using machines**

Diazepam can make you sleepy, forgetful, have poor coordination along with other side effects that can affect everyday activities (see Possible side effects). 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 receiving 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 taking this medicine.

### **Diazepam contains egg phospholipid and soya bean oil**

Diazepam contains egg phospholipid and soya bean oil. If you are allergic to eggs, peanut or soya, tell your doctor or nurse before being given this medicine.

### **Information on sodium content**

This medicine contains less than 1 mmol sodium (23mg) per ml, that is to say essentially 'sodium-free'.

### **3. How to use Diazepam**

Diazepam will be given by a doctor or a nurse as a slow intravenous injection (into a vein), or as a continuous infusion (into a vein).

Mix well before use.

#### **The recommended dose is:**

- **anxiety, agitation, muscle spasm, symptoms of alcohol withdrawal:** 10mg repeated at intervals of 4 hours, as required
- **tetanus:** 0.1-0.3mg per kg of body weight by intravenous injection repeated every 1-4 hours as required, or a continuous infusion of 3-10mg per kg of body weight every 24 hours
- **epilepsy:** initial dose of 0.15-0.25mg per kg of body weight by intravenous injection repeated in 30 to 60 minutes if required, and followed if needed by infusion up to 3mg per kg of body weight over 24 hours
- **before a general anaesthetic:** 0.1-0.2mg per kg of body weight by intravenous injection, should be adjusted to the patient's response
- **sedation before a minor operation or procedure:** 0.1-0.2mg per kg of body weight by intravenous injection. The normal adult dose is 10-20mg, but should be adjusted to the patient's response.

Your prescriber should have discussed with you how long the course of Diazepam will last. They will arrange a plan for stopping treatment. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms. Diazepam should be given for as short a period of time as possible. Your dose should be reduced gradually near the end of treatment.

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.

#### **If you are given more Diazepam than you should**

If you think you have had too much Diazepam, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include clumsiness and loss of coordination, feeling sleepy or deep sleep, speech problems, irregular or slow heartbeat, uncontrolled eye movement, muscle weakness or excitement. An

extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and breathing difficulties.

### **If you miss a dose of Diazepam**

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

### **If you stop being given Diazepam**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your medicine suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

If you have any further questions on the use of this medicine, ask your doctor, nurse 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 treatment:**

### **Uncommon (may affect up to 1 in 100 people)**

- Respiratory depression (very slow and/or shallow breathing)
- Allergic skin reactions in the form of itching, skin redness and swelling and skin rash.

### **Rare (may affect up to 1 in 1,000 people)**

- Respiratory arrest (cessation of breathing)
- Unconsciousness
- Jaundice (yellowing of your skin or the white of your eyes)
- Blood disorders (you may develop sore throats, nose bleeds or infections)

- Heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest).

**Very rare (may affect up to 1 in 10,000 people)**

- 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
- Low levels of white blood cells (leukopenia).

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

- Temporary stopping of breathing.

**Other side effects:**

**Very common (may affect more than 1 in 10 people)**

- Drowsiness.

**Common (may affect up to 1 in 10 people)**

- Fatigue
- Withdrawal symptoms (headache, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability, sleep disturbance, diarrhoea and mood changes)
- Confusion
- Loss of coordination of muscle movements (ataxia) and other movement disorders, tremor.

**Uncommon (may affect up to 1 in 100 people)**

- Muscle weakness
- Memory loss
- Difficulty in concentrating
- Balance disorders
- Dizziness
- Headache
- Slurred speech
- Stomach and intestinal problems such as nausea, vomiting, constipation, diarrhoea
- Increased salivation.

**Rare (may affect up to 1 in 1,000 people)**

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, memory loss, delusion, rages, psychoses, nightmares or hallucinations. These may be or become serious and are more likely to occur in children or the elderly. Talk to your doctor.
- Decreased alertness
- Depression
- Lack of feeling emotions (emotional poverty)

- Insomnia (problems sleeping)
- 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 (leakage of urine)
- Enlargement of breasts in men
- Impotence, changes in sexual drive (libido).

**Very rare (may affect up to 1 in 10,000 people)**

- Higher level of a certain enzyme in the blood (transaminase).

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

- Dependence and addiction (see section “How do I know if I am tolerant or addicted?”)
- Blurred vision, double vision and involuntary eye movements (these side effects disappear after you have stopped taking diazepam).

**Drug Withdrawal**

When you stop taking Diazepam, you may experience drug withdrawal symptoms, see section 3 “If you stop being given Diazepam”.

**How do I know if I am tolerant or addicted?**

If you notice any of the following signs whilst taking Diazepam, it could be a sign that you have become addicted:

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber.

**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](http://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**

Keep this medicine out of the sight and reach of children.

Store below 25°C. **Do not freeze.**

Do not use this medicine after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Do not throw away any medicines 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 Diazepam contains:**

- The active substance (the ingredient that makes the medicine work) is diazepam.
- The other ingredients are soya bean oil, monoglycerides, egg phospholipids, glycerol, sodium hydroxide, and water for injections.

### **What Diazepam looks like and contents of the pack**

Diazepam is a white, milky fluid.

Pack sizes are in boxes of 10x2ml ampoules.

### **Marketing Authorisation Holder:**

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### **Manufacturers:**

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