

DIAZEPAM 2 mg, 5 mg and 10 mg TABLETS

PACKAGE LEAFLET INFORMATION FOR THE USER

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 get 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 take Diazepam
3. How to take Diazepam
4. Possible side effects
5. How to store Diazepam
6. Further information

1 WHAT DIAZEPAM IS AND WHAT IT IS USED FOR

Diazepam Tablets belong to a group of drugs called benzodiazepines which promote sleep and relieve anxiety by altering brain activity concerned with emotion.

Diazepam is used:

- for the short term (2 – 4 weeks) relief of severe anxiety
- to relax muscles
- for the short term relief of difficulty in sleeping (when it is severe and causing distress)
- to relax or sedate people undergoing certain uncomfortable medical procedures.

2 BEFORE YOU TAKE DIAZEPAM

DO NOT take Diazepam if you:

- are allergic (hypersensitive) to Diazepam or benzodiazepines, or any of the other ingredients of this medicine
- have long-term or severe liver problems
- suffer from severe breathing problems
- suffer from sleep apnoea (difficulty breathing while asleep)
- suffer from myasthenia gravis (a disorder where muscles become weak and tire easily)
- suffer from mental illness, such as phobias, or obsessions.

Diazepam should NOT be taken on its own to treat depression or anxiety associated with depression.

Take special care with Diazepam

Tell your doctor before you start to take this medicine if you:

- have suffered a loss or bereavement
- have lung problems
- have liver problems
- suffer from personality disorders
- have had problems with alcohol or drug abuse.

Other important things to remember when taking Diazepam:

- When taking this medicine there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse, or suffer from a personality disorder.
- When stopping this medicine you may experience withdrawal effects (see section 3, If you stop taking Diazepam)
- Behavioural effects may occur while taking Diazepam (see section 4, Possible Side Effects)
- To reduce the risk of amnesia (loss of memory), you should make sure that you are able to have an uninterrupted sleep of at least 7 hours
- Tell the hospital or dentist you are taking Diazepam if you are to have an operation requiring an anaesthetic.

Taking other medicines

Talk to your doctor if you are taking any of the following:

- **anxiolytics/sedatives** e.g. lorazepam, buspirone
- **hypnotics** e.g. temazepam, zopiclone
- **anti-epileptic drugs** e.g. phenytoin or phenobarbital
- **anti-depressants** e.g. amitriptyline, fluvoxamine or fluoxetine
- **antipsychotics** (used for mental disorders) e.g. chlorpromazine, haloperidol
- **antihistamines** with a sedative effect (for allergies) e.g. chlorphenamine, promethazine
- **strong painkillers** e.g. codeine, co-proxamol
- **drugs which affect the way Diazepam is broken down by the liver** e.g. cimetidine, omeprazole or rifampicin (for tuberculosis)
- **claspriide** (used to treat gastric reflux).

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

Taking Diazepam with food and drink

- **DO NOT drink alcohol** while taking these tablets, as it may increase the sedative effect of the drug.

Pregnancy and breast-feeding

- If you are pregnant, planning to become pregnant or breast-feeding ask your doctor or pharmacist for advice before taking this medicine.
- If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing and feeding difficulties. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms.

Driving and using machines

- Your tablets may make you confused, forgetful, drowsy, unsteady or affect your co-ordination. These effects may be increased if you have not had enough sleep. **DO NOT drive or operate machinery** if you are affected.

Important information about some of the ingredients of Diazepam Tablets

- Patients who are intolerant to lactose should note that Diazepam Tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- The 5 mg tablet contains E110 (sunset yellow), which may cause allergic reactions.

3 HOW TO TAKE DIAZEPAM

Always take Diazepam Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should continue to take these tablets for as long as your doctor tells you to. The tablets should be swallowed with a drink of water.

Your doctor will decide on the correct dosage; the usual dose is:

Anxiety:

- **Adults:** 2 mg three times daily. If your symptoms are severe you may be given 15 – 30 mg daily taken in divided doses.

Muscle spasm:

- **Adults:** 2 – 60 mg daily taken in divided doses.
- **Children:** 2 – 40 mg daily taken in divided doses.

For both adults and children the dose is dependent on the symptoms, your doctor will decide on the correct dosage.

Trouble in sleeping associated with anxiety:

- **Adults:** 5 – 15 mg before going to bed. Do not take more than the maximum dose.

Pre-medication:

- **Adults:** 5 – 20 mg
- **Children:** 2 – 10 mg

Children:

Your doctor will want to carefully assess children given Diazepam and keep length of treatment as short as possible.

Elderly and Debilitated (very frail) patients:

Normally the starting dose is half of the ordinary adult dose.

Patients with liver problems:
Your doctor may prescribe a lower dose.

Long-term use of Diazepam is not recommended. Treatment should not normally last more than 4 weeks for sleeping problems or 2–3 months for anxiety.

You may become tolerant to the effects of Diazepam after you have been taking it for a few weeks. If you notice that the tablets are not working as well as they did when you first started taking them, you should go and see your doctor as an adjustment to your dosage may be required.

If you take more Diazepam than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause drowsiness, difficulty in controlling movements, slurred speech and involuntary eye movements. Coma, low blood pressure and breathing problems can also occur.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Diazepam
If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten tablet.

If you stop taking Diazepam
DO NOT stop taking your tablets suddenly, or without your doctor telling you, as you may suffer from **withdrawal effects**. If your doctor decides to stop your tablets, they will reduce the dose gradually to minimise any withdrawal effects, which may include:

- headache, muscle pain, tension
- severe anxiety, confusion, restlessness and irritability
- **In severe cases** of withdrawal you may experience a feeling of things being unreal, a feeling of detachment from your surroundings, numbness and tingling in the hands and feet, sounds seeming to be louder than usual and which can sometimes be painful if the sound is loud, sensitivity to light or touch, hallucinations and fits.

Even when you stop taking Diazepam gradually, you may feel anxious, depressed and restless and have difficulty sleeping. You may also experience sweating and diarrhoea. If this happens go to your doctor for advice.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Diazepam can cause side effects, although not everybody gets them.

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you suffer from:

- behavioural changes such as restlessness, agitation, irritability, aggressiveness, delusions, rages, nightmares, hallucinations, psychiatric disorders and inappropriate behaviour, as your treatment may be stopped.

The most common side effects are:

- tiredness
- drowsiness
- reduced alertness
- muscle weakness.

These effects are usually more common at the start of therapy but decrease on continuing treatment.

Other side effects are:

- loss of memory, difficulty sleeping, anxiety, confusion (particularly in the elderly), depression
- difficulty in controlling movements, shaking
- dizziness, blurred or double vision, slurred speech
- nausea, vomiting, stomach problems, diarrhoea, constipation, the production of too much or too little saliva
- headache
- low blood pressure
- changes in sexual desire
- skin reactions
- incontinence or problems passing urine.

Very rarely, jaundice (characterised by the yellowing of the skin or the whites of the eyes) and increased levels of liver enzymes in the blood may occur.

Withdrawal effects are known to occur (see section 3, **if you stop taking Diazepam**).

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

5 HOW TO STORE DIAZEPAM

Keep out of the reach and sight of children.

These tablets should be stored at or below 25°C and protected from moisture and light in the package or container supplied. Do not transfer them to another container. Do not use Diazepam after the expiry date that is stated on the outer packaging. 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 FURTHER INFORMATION

What Diazepam Tablets contain:

- The active ingredient is diazepam, 2 mg, 5 mg, or 10 mg.
- The other ingredients are lactose monohydrate, powdered cellulose, maize starch and magnesium stearate (E572). The 5 mg tablet also contains the colours quinoline yellow (E104) and sunset yellow (E110). The 10 mg tablet contains the colour indigo carmine (E132).

What Diazepam Tablets look like and contents of the pack:

- Diazepam Tablets 2 mg are white, flat, bevel edged tablets. They are engraved "Berk 2" with a breakline on reverse or "2" with a breakline on reverse.
- Diazepam Tablets 5 mg are yellow, flat, bevel edged tablets. They are engraved "Berk 5" with a breakline on reverse or "5" with a breakline on reverse.
- Diazepam Tablets 10 mg are blue, flat, bevel edged tablets. They are engraved "Berk 10" with a breakline on reverse or "10" with a breakline on reverse.

The 2 mg and 5 mg tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 250, 1000, 5000, 20000 or 10 x 50.

The 10 mg tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 200, 500, 1000 or 20000.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised: May 2008

PL 00289/0164-0166



83648-U