PATIENT INFORMATION LEAFLET

DIAZEPAM TABLETS

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE.
KEEP THIS LEAFLET UNTIL YOU HAVE FINISHED ALL THE PRESCRIBED COURSE OF DIAZEPAM.
IF YOU HAVE ANY QUESTIONS CONCERNING YOUR MEDICINE ASK YOUR DOCTOR OR PHARMACIST FOR MORE INFORMATION.

What is in Diazepam tablets?
The active ingredient of this medicine is Diazepam BP.
Diazepam tablets come in three strengths:

- **Diazepam 2 mg tablets** which contains 2mg Diazepam, together with the ingredients Lactose, Maize starch, Pregelatinised maize starch and Magnesium stearate (E572).
- **Diazepam 5 mg tablets** which contains 5mg Diazepam, together with the ingredients Lactose, Maize starch, Pregelatinised maize starch, Magnesium stearate (E572) and Quinoline yellow (E104).
- **Diazepam 10 mg tablets** which contains 10mg Diazepam, together with the ingredients Lactose, Maize starch, Magnesium stearate (E572) and Indigo carmine DFC blue 2 (E132).

Diazepam 2mg is a round, flat, white tablet with bevelled edges and embossed 2mg/DDSA.
Diazepam 5mg is a round, flat, pale yellow tablet with bevelled edges and embossed 5mg/DDSA.
Diazepam 10mg is a round flat, pale blue tablet with bevelled edges and a scoreline, and is embossed Tensium.

All three strengths are available in containers of 50, 100, 500 and 1,000 tablets.

Diazepam belongs to a group of medicines, the benzodiazepines that slow down the nervous system and are known as Central Nervous System (CNS) depressants.

The name and address of the Product Licence holder of Diazepam is:
Chelonia Healthcare Limited, Boumpoulinas 11, 3rd Floor, Nicosia, P. C. 1060, Cyprus

The name and address of the manufacturer of Diazepam is:
Meridian Healthcare (UK) Ltd., 208-214 York Road, Battersea, London SW11 3SD

Why have you been prescribed Diazepam?
In adults Diazepam is used for the short-term relief (2 - 4 weeks only) of nervousness or tension which is disabling or which can cause unacceptable distress either on its own or together with trouble in falling asleep or in sleeping, known as insomnia.
Diazepam is also used to help relax muscles or relieve muscle spasm which may occur with conditions such as fibrositis and arthritis, bursitis and cervical spondylitis, and to treat certain types of seizure such as those of epilepsy and tetanus.
Diazepam is used for the treatment of the symptoms of alcohol withdrawal.
Diazepam is also used for premedication for dental and surgical procedures.

In children Diazepam is used for the treatment of sleepwalking (somnambulism) and nightmares (night terrors). It is also used in certain conditions to help relax muscles and relieve muscle spasm.
Diazepam is also used for premedication for dental and surgical procedures.

BEFORE TAKING THIS MEDICINE
Before taking this medicine tell your doctor if you have ever had any unusual or allergic reactions to diazepam or other benzodiazepines. Also tell your doctor or pharmacist if you are allergic to any other substances, such as foods, preservatives or dyes.

The presence of other medical problems
The presence of other medical problems may affect the use of this medicine. Make sure, therefore, to tell your doctor if you have any other medical problems, especially:

- Any condition that affects your breathing, such as asthma, emphysema.
- Any liver or kidney problems for which you have or are receiving treatment.
- Raised eyeball pressure (Glaucoma)
- Depression

The effect of taking Diazepam with other medicines
This medicine will add to the effects of alcohol and other medicines that slow down the Central Nervous System (CNS), possibly causing drowsiness. Some examples of CNS depressants are antihistamines (medicines for hayfever and other allergies); sedatives; tranquillisers, sleeping medicines; pain relieving medicines; barbiturates; medicines for seizures; muscle relaxants; anaesthetics including some dental anaesthetics.

Make sure you doctor is informed of any medication you are taking, whether it has been prescribed or bought without a prescription. It is particularly important that your doctor is aware of any medicines you are taking which have been mentioned in the paragraph above.

If you go to a doctor, dentist or hospital for any reason, tell them you are taking Diazepam.

PRECAUTIONS WHILE USING THIS MEDICINE

Driving and using machines
When Diazepam has been combined during treatment with CNS depressants, sedative effects of these are likely to be intensified, and may last for a few days after you have stopped taking this medicine. Diazepam can affect your ability to drive and use machines as it may make you feel sleepy and dizzy. **Do not** drive or operate dangerous machinery 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:
  - Diazepam 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.

Please remember that alcohol may intensify these effects and should be avoided during treatment.

**Use in Pregnancy**

Do not take this medicine if you are pregnant, might become pregnant, or are breast-feeding. 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.

**PROPER USE OF THIS MEDICINE**

Take this medicine by mouth and only in the doses prescribed by your doctor. Do not take more of it and do not take it more often or for a longer time than your doctor ordered. If you are taking this medicine for nervousness or confusion or insomnia (trouble in sleeping), check with your doctor at four-weekly intervals to make sure you need to continue taking this medicine. If your doctor decides that treatment should be stopped, then Diazepam will be withdrawn gradually; even then symptoms such as depression, nervousness, insomnia, irritability, sweating and diarrhoea may occur.

If you are taking this medicine for epilepsy or other seizure disorders, it must be taken every day in regularly spaced doses as ordered by your doctor. This is necessary to keep a constant amount of the medicine in the blood. To keep this amount constant it is best not to miss any doses.

Stopping Diazepam after a long period of treatment may cause seizures (convulsions).

If you feel this medicine is not working as well after you have taken it for a short time (1-2 weeks) do not increase the dose, instead check with your doctor.

**If you miss a dose**, skip the missed dose and go back to your regular dosing schedule. **Do not double the dose.**

**Common dosages:**

*For anxiety states:*
The lowest dose should be used that can control symptoms. Treatment will not normally be continued beyond 4 weeks.

*Mild anxiety states: 2 mg (one Diazepam 2 mg tablet) three times daily.*

*Severe anxiety states: 15 mg to 30 mg (three Diazepam 5 mg tablets to three Diazepam 10 mg tablets) daily in divided doses.*

*Symptomatic relief of acute alcohol withdrawal: 5 mg to 20 mg (one Diazepam 5 mg tablet to two Diazepam 10 mg tablets) repeated if necessary in 2 to 4 hours.*

*Insomnia associated with anxiety: 5 mg to 15 mg (one Diazepam 5 mg tablet to three Diazepam 5 mg tablets) before retiring. This treatment should not be used on a routine basis but intermittently as directed by your doctor.*

*Conditions associated with muscle spasm:*
The selected dose should relate to the severity of the case which your doctor will judge of.

*Muscle spasm: 2 to 15 mg (one Diazepam 2 mg tablet to three Diazepam 5 mg tablets) daily in divided doses.*

*Management of muscle spasm of brain origin: 2 to 60 mg (one Diazepam 2 mg tablet to six Diazepam 10 mg tablets) daily in divided doses.*

*As an aid to the control of muscle spasm in tetanus: 3 to 10 mg/kg bodyweight daily.*

*As an aid to the management of some types of epilepsy: 2 to 60 mg (one Diazepam 2 mg tablet to six Diazepam 10 mg tablets) daily in divided doses.*

*Premedication: 5 to 20 mg (one Diazepam 5 mg tablet to two Diazepam 10 mg tablets).*

**Treatment should always be tapered off gradually.**

**Children:**

*Dosages for sleepwalking (somnambulism): 1 to 5 mg (1/2 Diazepam 2 mg tablet to one Diazepam 5 mg tablet) at bedtime.*

*Conditions associated with muscle spasm:*

*Control of tension and irritability in muscle spasm of brain origin: 2 to 40 mg (one Diazepam 2 mg tablet to four Diazepam 10 mg tablet) daily in divided doses.*
As an aid to control the muscle spasm in tetanus: 3 to 10 mg per kg bodyweight.

Premedication: 2 to 10 mg (one Diazepam 2 mg tablet to one Diazepam 10 mg tablet).

Elderly and debilitated patients: Doses should not exceed half those normally recommended.

What to do if too many tablets are taken at the same time.
If you think you may have taken an overdose of this medicine obtain emergency help at your nearest hospital casualty department or doctor. Some signs of an overdose are continuing slurred speech or confusion, severe drowsiness, severe weakness and staggering. Tell the doctor in charge, or the nurse, or pharmacist that you are taking this medicine and take any remaining tablets in their original container with you.

WHAT SIDE EFFECTS CAN DIAZEPAM HAVE?
Children and the elderly are usually more sensitive to the effects of Diazepam and most of the side effects of this medicine are more likely to occur in these patients. Along with its needed effects, the medicine may cause some unwanted effects, which may persist into the next day. Common amongst these include drowsiness, sedation, unsteadiness and difficulty with balance when walking. Loss of memory may also occur.

Other adverse effects are rare and include headache, dizziness, lowering of blood pressure, stomach upsets, skin rashes, visual disturbances, changes in sexual desire, difficulty in urinating, jaundice (yellow discoloration of eyes and skin), and anaemic conditions causing unusual bruising or bleeding. If any of the above effects become troublesome check with your doctor as soon as possible.

These side effects will become more noticeable if you are taking anti-epileptic drugs.

When taken for trouble in sleeping (insomnia) by the elderly more daytime drowsiness may be experienced than in younger adults. In elderly patients falls and related injuries may be more likely to occur.

Rarely, aggressive outbursts of anger, excitement and confusion may be experienced. If this occurs check with your doctor at once as they may wish you to discontinue using the drug.

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

Storing your medicine
Keep out of the sight and reach of children.

Keep your medicine in a dry place, below 25°C. Protect from light. Keep the tablets/capsules in the container in which they were given to you.

If your doctor tells you to stop the treatment, return any remaining tablets/capsules to the pharmacist.

A reminder
REMEMBER this medicine is for you. Never give it to someone else, even if their symptoms are the same as yours.

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

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