PACKAGE LEAFLET: INFORMATION FOR THE USER
Diazepam 2mg Tablets, Diazepam 5mg Tablets,
Diazepam 10mg Tablets
Diazepam
(Referred to as Diazepam Tablets in this leaflet)

Read all of this leaflet carefully before you start to take this medicine.
− Keep this leaflet. You may need to read it again while you are receiving your treatment.
− If you have any further questions, please 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 Tablets are and what they are used for
2. Before you take Diazepam Tablets
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1. What Diazepam Tablets are and what they are used for

The name of your medicine is Diazepam Tablets; the active ingredient is diazepam. This medicine belongs to a group of medicines called benzodiazepines. Diazepam Tablets are used:
- to treat anxiety
- to treat Insomnia (difficulty sleeping)

2. Before you take Diazepam Tablets

You should NOT be given Diazepam Tablets if you:
- are allergic (hypersensitive) to diazepam, any other benzodiazepines or to any of the other ingredients in Diazepam Tablets (see section 6, Further information)
- are suffering from phobias (irrational fears) or obsessions
- have breathing problems
- suffer from obstructive sleep apnoea (a condition where you stop breathing during sleep)
- have severe liver disease
- have suffered recent loss or bereavement as diazepam can cause memory loss
- suffer from depression, anxiety or other long standing mental illness, for which you are not being treated

Talk to your doctor before being given Diazepam Tablets if you:
- have kidney or liver disease
- suffer from porphyria (a disease of blood proteins affecting the skin, gut and nervous system)
- suffer from myasthenia gravis (a disease of the nervous system causing muscle weakness)
- have a history of alcohol and/or drug abuse
- suffer from brain disease (particularly diseases affecting the blood circulation of the brain)
- have a personality disorder, suicidal tendencies or are prone to aggressive episodes or self-harm

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The following medicines can affect or be affected by treatment with Diazepam Tablets:
- medicines used to treat bacterial infections (e.g. erythromycin)
- medicines used to treat depression (e.g. fluvoxamine)
- medicines used to treat fits (e.g. carbamazepine, phenytoin and sodium valproate)
- medicines used in surgery (anaesthetics) and strong pain killers (narcotic analgesics e.g. fentanyl)
- medicines used to treat allergies and insect bites (antihistamines)
- medicines used to treat high blood pressure (alpha-blockers e.g. moxonidine)
- medicines used to treat psychosis, schizophrenia and other mental illnesses (e.g. clozapine and zotepine)
- medicines used to treat HIV infection (e.g. amprenavir and ritonavir)
- medicines used to treat anxiety and sleep disturbance (e.g. nitrazepam)
- digoxin (used to treat abnormal heart rhythms and heart failure)
- disulfiram (used to treat alcoholism)
- levodopa (used to treat Parkinson's Disease)
- lofexidine (used to reduce symptoms of heroin withdrawal)
- baclofen and tizanidine (muscle relaxants)
- nabilone (used to treat nausea and nerve pain)
- oral contraceptives ("The Pill")
- theophylline (used in asthma and lung diseases)
- cimetidine and omeprazole (used to treat problems with stomach acid and ulcers).

Taking Diazepam Tablets with food and drink
You should avoid smoking and drinking alcohol whilst taking this medicine.

Pregnancy and breast-feeding
You should not take this medicine if you are pregnant or breastfeeding (unless your doctor decides it is essential). Tell your doctor straight away if you think you may be pregnant or intend to start a pregnancy.

There may be a slight increase in abnormalities, particularly hare lip, in babies born to mothers given benzodiazepines during the first three months of pregnancy. Babies exposed to benzodiazepines during pregnancy may be slow developers. If a mother has received diazepam towards the end of pregnancy or during labour, the baby may be affected, with feeling cold, floppiness, difficulty breathing and suckling, or withdrawal symptoms. If you experience any side effects or feel that the medicine is affecting you badly tell your doctor immediately.

Driving and using machinery
Diazepam Tablets may affect your muscles or make you feel sleepy or forgetful (especially if you don't have enough sleep). If you are affected in this way, do not drive or use any tools or machinery.
This medicine can affect your ability to drive.
Do not drive whilst taking this medicine until you know how this medicine affects you.
It may be an offence to drive if your ability to drive safely is affected.
There is further information for patients who are intending to drive in Great Britain - go to http://www.gov.uk/drug-driving-law
Important information about some of the ingredients in Diazepam Tablets
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Diazepam Tablets

Your doctor will decide the right dose for you. The dosage depends on the condition being treated, weight and age. The actual dose will depend on your condition and may be reduced if you are elderly or very run down or if you have liver or kidney problems. If you do not understand what you are being given then ask your doctor or nurse. Unless otherwise directed, take your tablet with water at night.

The usual doses are as follows:
Adults
For anxiety:
- 15 to 30 mg each day for no more than 8 to 12 weeks

For insomnia
- 5 to 15 mg at night for no more than 4 weeks

A lower dose of diazepam may be given to you if you have severe problems with your breathing. Diazepam Tablets are not recommended for use in children.

If you take more Diazepam Tablets than you should
If you accidentally take too many tablets you should contact your doctor, pharmacist or nearest hospital casualty department immediately. Take this leaflet and any tablets you have left to show the doctor or pharmacist.

If you forget to take Diazepam Tablets
If you forget to take a tablet, take your next tablet at the next correct time and continue your course. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Diazepam Tablets
Dependence on diazepam and other benzodiazepines can occur when used over a long time and is more common in patients with a history of drug or alcohol abuse. The risk of dependence is low in small doses given over short periods. If you have needed treatment with diazepam over a long period, your doctor will not stop treatment immediately but will gradually reduce your dose over time to stop withdrawal symptoms such as anxiety, depression, stomach cramps, nausea and sweating.

4. Possible side effects

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

As can happen with any medicine, a few people may develop an allergic reaction. If you experience any of the following, tell your doctor immediately:
- rash, itching, swelling of the face and eyes, difficulty breathing.
- if you feel restless, have nightmares or notice behavioural changes after taking diazepam
- blood disorders (you may develop a sore throat, nose bleeds or infections)
- chest pain, slow pulse, slow heart rate, stopping breathing during sleeping, yellow skin (jaundice).

Rarely instead of feeling sleepy, opposing effects may be seen in some patients especially in children or elderly which include aggressive behaviour, irritability, over excitement, increased anxiety, feeling “high” and difficult sleeping.

The side effects of diazepam are usually mild and infrequent.
Side effects that have been reported are:
- inability to pass water
- urinary incontinence
- raised liver enzymes
- clumsiness
- visual disturbances
- memory loss
- fatigue and a hangover effect
- stomach and gut problems
- increase in breast tissue in men
- dry mouth
- dizziness and unsteadiness which may cause falls
- slurred speech
- tremor
- rashes and other allergic reactions
- confusion
- anxiety, depression and other mental problems
- headaches
- sleep problems
- change in libido
- drowsiness
- breathing problems

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 www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diazepam Tablets

Keep out the reach and sight of children.
- Diazepam Tablets should be stored in a cool dry place, protected from light in the package or container in which they were given to you. Do not transfer diazepam to another container.
- Diazepam Tablets should not be taken after the expiry date on the label; the expiry date refers to the last day of the month, your doctor will check this.
- Diazepam Tablets should not be taken if the tablets show signs of "going off" such as discoloration.

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 protect the environment.

6. Further information

What Diazepam Tablets contain

The active ingredient is diazepam. Each tablet contains 2mg, 5mg or 10mg diazepam. The other ingredients are lactose, maize starch, povidone, sodium starch glycollate and magnesium stearate.

The tablets also contain:
5mg: lake quinoline yellow (E104)
10mg: indigo carmine (E132)

What Diazepam Tablets look like and the contents of the pack
Diazepam 2mg Tablets are circular, white, flat faced tablets with bevelled edges embossed with D/2 on one face and CP on the reverse.

Diazepam 5mg Tablets are circular, pale yellow, flat faced tablets with bevelled edges embossed with D/5 on one face and CP on the reverse.

Diazepam 10mg Tablets are circular, pale blue, flat faced tablets with bevelled edges embossed with D/10 on one face and CP on the reverse.

Diazepam Tablets are available in amber glass bottles of 50 tablets and polypropylene or polyethylene containers containing 500, 1,000, 5,000 and 20,000 tablets or blister packs of 28 tablets.

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only).
Please be ready to give the following information

Product name	Reference number
Diazepam 2mg Tablets	PL 53797/0073
Diazepam 5mg Tablets	PL 53797/0074
Diazepam 10mg Tablets	PL 53797/0075

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder:
Austin McNeil Ltd.,
772 Fulham Road, London,
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Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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