# **DIAPO TABLET**

Diazepam (5mg)

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## What Diapo is used for

The name of your medicine is Diapo. It contains the active ingredient diazepam.

This medicine is used to:

- Treat anxiety disorders
- Control muscle spasms and relax muscles
- Treat symptoms associated with alcohol withdrawal, such as trembling and agitation.
- hypnotic in short-term management of insomnia
- as an anticonvulsant
- treatment of tension headache

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

## **How Diapo works**

This medicine belongs to a group of medicines called benzodiazepines. It is thought to work by acting on chemicals in the brain.

Benzodiazepines act as depressants of the central nervous system (CNS) producing CNS depression from sedation to hypnosis to coma depending on dose.

Benzodiazepines should not be used alone to treat depression or severe mental illness.

In general, benzodiazepines such as diazepam should be taken for short periods only.

Continuous long-term use is not recommended unless advised by your doctor.

There is evidence that using these types of medicines can lead to dependence.

#### Before you use Diapo

When you must not use it

Do not take this medicine if:

- You have severe lung disease
- You suffer from sleep apnoea (temporary stops in breathing during sleep)
- You suffer from myasthenia gravis (a disease which causes severe muscle weakness)
- You are addicted to drugs or alcohol (unless your doctor has prescribed diazepam to help to relieve the symptoms of alcohol withdrawal)
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn or shows signs of tampering or it does not look quite right.

You are hypersensitive to, or have had an allergic reaction to, diazepam, any of the ingredients listed at the end of this leaflet or other benzodiazepines.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty of breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the nearest hospital.

If you are not sure whether you should start taking this medicine, talk to your doctor.

#### - <u>Before you start to use it</u>

Before you start taking this medicine, tell your doctors if:

- 1. You have allergies to:
- Any other medicines
- Any other substances, such as foods, preservatives or dyes.
- Lactose, these tablets contain lactose
- 2. You have or have had any medical conditions, especially the following:
- liver, kidney or lung problems.
- narrow or acute angle glaucoma (raised pressure in the eye)
- memory loss
- depression, psychosis or schizophrenia
- Epilepsy.
- 3. You drink alcohol. Alcohol may increase the effects of diazepam and for example may result in excessive drowsiness.

The same effect may also be seen with other medicines which make you sleepy.

- 4. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
- 5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

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- 6. You are planning to have surgery or an anaesthetic.
- 7. You are currently receiving or are planning to receive dental treatment.

## - Taking other medicines

Before you start taking this medicine, tell your doctors if you are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines can interfere with your treatment. Tell your doctor if you are taking or planning to take any of the following:

- oral estrogen-containing contraceptives, erythromycin or isoniazid, rifampicin and clozapine
- other sleeping tablets, sedatives or tranquillisers
- medicines used to treat mental disorders, including depression
- medicines used to treat epilepsy
- medicines for allergies or colds (e.g. antihistamines)
- atropine and similar medicines, used for stomach problems, in operations and also sometimes after heart attacks
- strong pain relievers
- anaesthetics (used during operations)
- cimetidine, omeprazole or medicines used to treat ulcers or reflux
- disulfiram, a medicine used to help treat alcoholism

These medicines may be affected by diazepam or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other interactions not listed above may also occur.

## How to use Diapo

Follow carefully all directions given to you by your doctor. They may differ

from the information contained in this leaflet.

#### - How much to use

Take diazepam only as directed by your doctor.

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition and whether you are taking any other medicines.

The usual adult dose is usually between 2 mg to 10 mg two to four times daily depends of the reason of prescription.

Children, elderly and very ill patients may need to take less.

Do not stop taking your medicine suddenly, or change the dosage, without checking with your doctor.

When it is time to stop taking diazepam your doctor will tell you how to do this gradually.

#### - When to use it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

#### - How long to use it

Continue taking your medicine for as long as your doctor tells you.

Usually, diazepam should be taken for short periods only. Continuous long term use is not recommended unless advised by your doctor.

Dependence may develop from using benzodiazepines such as diazepam.

# - If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

# - <u>If you use too much(overdose)</u>

Immediately telephone your doctor for advice, or go to your nearest hospital, if you think that you or anyone else may have taken too much diazepam. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Also report any other medicine or alcohol which has been taken.

If you take too much diazepam, you may feel drowsy, confused, and dizzy, have difficulty breathing, feel weak or become unconscious. It is important that you recognise these signs of overdose early.

## While you are using it

## - Things you must do

Tell your doctor that you are taking this medicine if:

- You are about to be started on any new medicine
- You are pregnant or are planning to become pregnant
- You are breastfeeding or are planning to breast-feed
- You are about to have any blood tests
- You are going to have surgery or an anaesthetic or are going into hospital.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition. Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

#### - <u>Things you must not do</u>

#### Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor. Stopping this medicine suddenly may cause some side effects such as disturbed sleep. Also, if you suffer from epilepsy, stopping this medicine suddenly may make your epilepsy worse.

Your doctor may decide to slowly reduce your dose of diazepam before you can stop taking it completely.

Do not let yourself run out of medicine on weekends or holidays.

#### - Things to be careful of

### Be careful:

- Driving or operating machinery until you know how diazepam affects you. This medicine may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, or operate machinery or do anything else that is dangerous.
- When drinking alcohol while taking diazepam.
- Combining diazepam and alcohol can make you more sleepy, dizzy or lightheaded.
- Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking this medicine.
- If you are elderly, unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness, unsteadiness and/ or a drop in blood pressure which may increase the risk of a fall.

#### **Side Effects**

Tell your doctor as soon as possible if you do not feel well while you are taking Diapo

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects.

Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- drowsiness, tiredness
- muscle weakness
- · clumsiness or unsteadiness
- feeling sick, dizzy, giddy of lightheaded
- loss of memory, inattentiveness, confusion, lack of concentration
- feeling depressed
- headache, hangover feeling in the morning
- problems speaking such as slurred speech
- · blurred or double vision
- incontinence
- · mild skin rash
- dry mouth or excessive saliva
- constipation, urinating less than normal
- Increased or decreased libido (sex drive).

Tell your doctor immediately or go to the nearest hospital if you notice any of the following:

These are very serious side effects and you may need urgent medical attention or hospitalisation.

- Sudden anxiety or excitation
- restlessness, agitation, irritability, anger, abnormal behaviour
- severe sleep disturbances
- Yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice).

Other side effects not listed above may occur in some patients.

# Allergic reactions:

If you think you are having an allergic reaction to Diapo, do not take any more of this medicine and tell your doctor immediately or go to the nearest hospital.

You may report any side effect or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5550, or visiting the website portal.bpfk.gov.my (Consumer – Reporting).

#### Storage and Disposal of Diapo

#### - Storage

Keep your medicine in its original packaging until it is time to take it. If you take your medicine out of its original packaging it may not keep well. Protect from light.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it. A locked cupboard at least one-anda- half metres above the ground is a good place to store medicines.

## - <u>Disposal</u>

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

# **Product Description**

## - What it looks like

A 8mm diameter, round, flat, scored yellow tablet.

## - Ingredients

Active Ingredient:

Each tablet contains Diazepam B.P. 5mg.

Inactive Ingredients

- Color, Quinoline Yellow
- Magnesium Stearate
- Corn Starch
- Lactose
- <u>MAL Number</u> MAL19861270A

#### Manufacturer

UPHA PHARMACEUTICAL MANUFACTURING (M) SDN BHD (53667-M)
Lot 2&4, Jalan P/7, Seksyen 13, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

# **Product Registration Holder**

UPHA PHARMACEUTICAL MANUFACTURING (M) SDN BHD (53667-M)
Lot 2&4, Jalan P/7, Seksyen 13, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

# **Date of Revision**

11/11/2014

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