

# APO-DIAZEPAM TABLET

Diazepam (5mg, 10mg)

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## What Apo-Diazepam is used for

Apo-Diazepam(Diazepam) is useful in symptomatic relief of excessive anxiety and tension in psychoneurotic (maladaptive emotional behaviour) patients.

In acute alcoholic withdrawal, diazepam may be useful in the symptomatic relief of acute agitation, tremor and impending acute delirium tremens (an acute, sometimes fatal episode of delirium that is usually caused by withdrawal from chronic alcoholism, involving tremors, anxiety, hallucinations [hearing voices or seeing images that are not really there], and disorientation).

Diazepam is also a useful adjunct to the relief of spasticity in neuromuscular disorders (muscle spasms).

## How Apo-Diazepam works

Apo-Diazepam contains the active ingredient Diazepam. Apo-Diazepam belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

Diazepam possesses anxiolytic and sedative properties which may be of value in the symptomatic relief of manifest anxiety and tension states in psychoneurotic patients. It has also an adjunctive value in the relief of certain neurospastic conditions.

## Before you use Apo-Diazepam

### - When you must not use it

You must not use this medication if you are allergic to diazepam or any similar medication or any of the other

ingredients of Apo-Diazepam (see section **Product description**).

Do not use Apo-Diazepam if you have myasthenia gravis (weakness and rapid fatigue of muscles) or glaucoma (increased pressure in the eye)

### - Before you start to use it

Before you start to use this medication, your doctor needs to know if you :

- have any form of drug abuse/dependency history
- have depression, psychosis (loss of contact with reality) or other mental illness
- have had suicidal thoughts
- have a history of seizures (fits)
- have liver or kidney problems
- are elderly

### Pregnancy and lactation

Do not take Apo-Diazepam if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Diazepam if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You should not take medications such as:

- phenothiazine (medicine used to treat psychosis)
- barbiturates (medicines used to treat anxiety, sleeplessness, or seizures)
- monoamine oxidase inhibitors (MAOI) and other antidepressants

This is because some medication could cause complications when taken together with Apo-Diazepam.

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

## How to use Apo-Diazepam

### - How much to use

The dosage will be individualised for maximal therapeutic effect depending on your diagnosis, severity of symptoms and your response.

*Symptomatic relief of excessive anxiety and tension in psychoneurotic patients:*

The recommended dose is 4-40mg daily administered in divided doses 2-3 times daily.

*Adjunctively for the relief of spasticity in neuromuscular disorders:*

The recommended dose is 6-30mg daily in divided doses.

*Elderly and debilitated patients:*

The recommended initial dose is 2mg, once or twice daily; to be increased gradually as needed and tolerated.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue taking Apo-Diazepam for as long as your doctor recommends.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your

nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The main symptoms of diazepam overdosage are drowsiness, oversedation and ataxia (an impaired ability to coordinate movement).

**While you are using it**

- Things you must do

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Diazepam.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Stopping this medicine suddenly may cause some unwanted effects i.e. withdrawal symptoms (including convulsions). Your doctor will explain how you should slowly reduce your dose of Apo-Diazepam before you can stop taking it completely.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Diazepam to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or

use machines and contact your doctor immediately.

Do not drink alcohol while you are taking Apo-Diazepam. Alcohol may increase the sedative effects of Apo-Diazepam and make you very sleepy.

This medication might also cause complex sleep-related behaviors which may include sleep driving, making phone calls, preparing and eating food (while asleep).

**Side effects**

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

Tell your doctor if you notice any of the following and they worry you:

- drowsiness,
- ataxia,
- fatigue,
- dizziness,
- nausea,
- blurred vision,
- diplopia (seeing doubles),
- vertigo (a sensation of spinning or whirling motion) ,
- headache,
- slurred speech,
- tremors,
- hypoactivity (abnormally diminished activity),
- dysarthria (difficulty speaking caused by problems controlling the muscles used in speech),
- euphoria (a feeling or state of intense excitement and happiness),
- impairment of memory,
- confusion,
- depression,
- incontinence or urinary retention,
- constipation,
- skin rash

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

- leucopenia (reduction of white blood cells in the blood),
- jaundice (yellowish discoloration of skin),
- hypersensitivity or allergic reactions,
- paradoxical reactions (such as hyperexcited states, anxiety, excitement, hallucinations, increased

muscle spasticity, insomnia, rage, as well as sleep disturbances and stimulation).

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Other side effects not listed above may occur in some patients.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers →Reporting).

**Storage and Disposal of Apo-Diazepam**

- Storage

Keep out of the reach and sight of children.

Keep at tightly closed, light resistant container. Store at 15-30°C.

- Disposal

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.

**Product Description**

- What it looks like

Apo-Diazepam - round, flat-faced, bevelled edge, scored tablet.

5mg: yellow, identified "APO" over "5";

10mg: blue, identified "APO" over "10".

- Ingredients

- Active ingredient  
Diazepam

- Inactive ingredients  
5mg: Lactose Monohydrate, Microcrystalline Cellulose, Starch, Magnesium Stearate, D&C Tello #10 Aluminum Lake, 14-18%, Sunset yellow Aluminum Lake40%

10mg: Lactose Monohydrate,  
Microcrystalline Cellulose, Starch,  
Magnesium Stearate, Brilliant Blue  
FCF AL Lake, Indigotine AL Lake  
12-14% (Blue #2)

- MAL number(s):

Apo-Diazepam 5mg Tab  
MAL19984716ARZ

Apo-Diazepam 10mg Tab:  
MAL19984707ARZ

**Manufacturer**

Apotex Inc.,  
150 Signet Drive,  
Weston,  
Ontario, Canada M9L 1T9.

**Product Registration Holder**

Pharmaforte(M) Sdn Bhd  
2, Jalan PJU 3/49,  
Sunway Damansara,  
47810 Petaling Jaya,  
Selangor.

**Date of revision**

28/10/2015

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