

DIAZEPAM TABLET

Diazepam (5mg, 10mg)

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What Diazepam Tablet is used for

Diazepam Tablet is used to:

- Treat anxiety
- Treat acute alcohol withdrawal symptoms
- Relieve anxiety and tension before operative procedures.
- An adjunct prior to endoscopic procedures which allows for examination of the inside lining of your digestive tract
- Relieve of convulsive disorder
- Help to relax muscles and for muscle spasm
- Treat tremor

How Diazepam Tablet works

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

Before you use Diazepam Tablet

- *When you must not use it*

Do not take Diazepam Tablet and tell your doctor if you

- are allergic to diazepam or to other benzodiazepine medicines or to any of the other ingredients in your tablets (see section **Product description**).
- have acute-close angle glaucoma (high pressure in the eye)
- suffer psychotic disorder (mental illness)
- have myasthenia gravis (a condition which causes muscles to weaken and tire easily)
- severe breathing problems (severe obstructive disease)

- *Before you start to use it*

Check with your doctor or pharmacist before taking Diazepam Tablet if you

- are elderly or suffer severe weakness
- have arteriosclerosis (thickening or hardening of blood vessels)
- have liver or kidney problems
- have breathing difficulty

Pregnancy and breast-feeding

You should not take Diazepam Tablet if you are pregnant, planning to become pregnant or are breast feeding. If taken regularly during late pregnancy, your baby may develop withdrawal symptoms. Do not take Diazepam Tablet until you and your doctor have discussed the risks and benefits involved.

- *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, especially:

- antacids and cimetidine (help to reduce stomach acid).
- antidepressants (use to treat depression), e.g. tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs).
- medicine to relieve nausea, vomiting and dizziness associated with motion sickness, e.g. scopolamine.
- medicines for epilepsy e.g. phenytoin, carbamazepine, or sodium valproate.
- Rifampicin and isoniazid (to treat tuberculosis).
- levodopa (to treat Parkinson's Disease).

Other medicines not listed above may also interact with Diazepam Tablet.

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

How to use Diazepam Tablet

- *How much to use*

Usual Adults dose:

To help with anxiety: Orally, 2 to 10mg, two to four times a day.

To help with alcohol withdrawal

symptoms: Orally, 10mg, three or four times a day during the first 24 hours, the dosage being decreased to 5mg three or four times a day as needed.

To help with seizures or fits: Orally, 2 to 10mg three or four times a day.

To help with muscle spasms: Orally, 2 to 10mg three or four times a day.

Elderly or patients with severe weakness:

Orally, 2 to 2.5mg one or two times a day, the dosage being increased gradually as needed and tolerated.

Usual children dose:

Children up to 6 months of age: use is not recommended.

Children 6 months and above: orally, 1 to 2.5mg, three or four times a day, the dosage being increased gradually as needed and tolerated.

- *When to use it*

Use as directed by your doctor or pharmacist.

Swallow the tablets whole, with a glass of water.

- *How long to use it*

Take Diazepam Tablet only for as long as your doctor recommends. Usually, Diazepam Tablet should be taken for short periods only. Continuous long-term use is not recommended unless advised by your doctor. Long term use of Diazepam Tablet may lead to dependence (see section *Things to be careful of*).

- *If you forget to use it*

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

- *If you use too much (overdose)*

Immediately call your doctor or go to the emergency department at your nearest hospital if you or anyone else has taken a large amount of this medication.

If you take too many Diazepam tablet, you may experience confusion, severe drowsiness, shakiness, shortness of breath and severe weakness.

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While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the number of tablets you take before stopping them completely (see section Things to be careful of).

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

- Things to be careful of

Driving and using machines

Diazepam Tablet can make you sleepy. Avoid drinking or operating machinery while taking Diazepam Tablet.

Alcohol may increase the sedative effects of Diazepam Tablet and make you very sleepy. Do not drink alcohol while you are taking Diazepam Tablet. Elderly patients are more susceptible to these effects.

Complex sleep-related behaviours

Complex behaviours which may include sleep driving, making phone calls, preparing and eating food may occur while asleep.

Dependence

When taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse.

Withdrawal

Treatment should be gradually withdrawn. Sudden withdrawal can cause withdrawal symptom.

Side effect

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

Tell your doctor if you notice any of the following side effects:

- drowsiness
- ataxia (lack of muscular coordination)
- light-headedness

- memory loss
- low blood pressure
- breathing difficulties
- nausea
- constipation
- blurred visual
- skin rashes
- urination difficulty
- shaking
- confusion
- slurred speech
- changes in sex drive
- dependence

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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 (*Consumers Reporting*).

Storage and Disposal of Diazepam Tablet

- Storage

Keep out of the reach and sight of children.

Store below 25°C. Protect from light. Do not use Diazepam Tablet after the expiry date stated on the packaging. The expiry date refers to the last day of that month.

- 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

Clean, dry, uniform, round, flat, bevel edged tablets and scored on one side. Color: Yellow (5mg) & Blue (10mg).

Ingredients

- Active ingredient:
Diazepam

- Inactive ingredients:

Diazepam Tablet 5mg
Maize Starch, Lactose, D&C Yellow No. 10 and Magnesium Stearate.

Diazepam Tablet 10mg

Maize Starch, Lactose, FD & C Blue No. 1 and Magnesium Stearate.

- MAL numbers:

Diazepam Tablet 5mg:
MAL19860211AZ

Diazepam Tablet 10mg:

MAL19860211AZ

Manufacturer

Idaman Pharma Manufacturing Sdn. Bhd. (661901-P)
Lot 24 & 25 Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah Darul Aman, Malaysia.

Product Registration Holder

Idaman Pharma Manufacturing Sdn. Bhd. (661901-P)
Lot 24 & 25 Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah Darul Aman, Malaysia.

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