

MIZOLAM TABLET

Midazolam maleate (7.5mg)

Consumer Medication Information Leaflet (RiMUP)

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What Mizolam Tablet is used for

Mizolam Tablet is used for the short term treatment of insomnia (inability to sleep).

Mizolam Tablet may also be given to you before an operation to produce sleepiness or drowsiness and to relieve anxiety.

How Mizolam Tablet works

Mizolam Tablet belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

Mizolam Tablet will cause sedation and help you sleep. Your doctor, however, may have prescribed Mizolam Tablet for another purpose.

Ask your doctor if you have any questions about why Mizolam Tablet has been prescribed for you.

If you will be receiving Mizolam before minor surgery, your doctor will give you the medicine and closely follow your progress.

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

Before you use Mizolam Tablet

- When you must not use it

Do not take Mizolam Tablet if you:

- have had an allergic reaction to Mizolam Tablet, any other

benzodiazepine medicine, or any of the ingredients listed at the end of this leaflet.

- have severe muscle weakness also known as myasthenia gravis.
- have respiratory problems.
- have a condition called sleep apnea syndrome (a disorder in which you have one or more pauses in breathing while sleeping).
- have severe liver damage or liver disease.
- are suffering from shock, coma or acute alcoholic intoxication.
- are taking antifungal medicines such as ketoconazole, itraconazole or voriconazole.
- are taking a type of medicine for HIV called HIV protease inhibitors including ritonavir boosted protease inhibitors.
- suffer from galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

If you are not sure whether you should be given Mizolam Tablet, talk to your doctor.

Do not give Mizolam Tablet to children.

Do not take Mizolam Tablet if the expiry date printed on the pack has passed. If you do not find an expiry date on a repacked medication label, please ask from your pharmacist.

- Before you start to use it

Your doctor must know about all the following before you receive Mizolam Tablet.

1. If you are pregnant or plan to become pregnant. It is not known whether Mizolam Tablet is harmful to an unborn baby when given to a pregnant woman. If there is a need to use Mizolam Tablet when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.
2. If you are breastfeeding or plan to breastfeed, Mizolam Tablet may pass into the breast milk and cause drowsiness and/or feeding

difficulties in the baby. Mizolam Tablet is not recommended for use while breastfeeding.

3. If you have any other health problems including:
 - liver, kidney or lung disease
 - high or low blood pressure or heart disease
 - mental disorders such as depression, psychosis (mental illness which causes loss of contact with reality) or schizophrenia (mental disorder in which people interpret reality abnormally and with abnormal social behavior).
 - epilepsy (fits or convulsions)
4. If you drink alcohol or use illicit (illegal) drugs regularly. Use of benzodiazepines may lead to the development of physical and psychological dependence and the risk is increased with a history of alcohol or drug abuse. Tolerance of Mizolam Tablet may occur.
5. If you are allergic to any other medicines, foods, dyes or preservatives.

- 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.

Some medicines and Mizolam Tablet may interfere with each other. These include:

- antifungals (medicines used to treat fungal infections) e.g. ketoconazole, itraconazole, fluconazole
- antibacterials (medicines used to treat bacterial infections) e.g. erythromycin, clarithromycin
- calcium channel blockers (medicines used to treat high blood pressure, angina and arrhythmias) e.g. diltiazem, verapamil

- medicines used to treat HIV e.g. efavirenz
- other medicines used to induce sleep
- medicines used to inhibit stomach acid production e.g. cimetidine, ranitidine
- medicines used to treat epilepsy (fits) e.g. carbamazepine, phenytoin
- medicines used to treat tuberculosis (infectious disease which affects the lungs) e.g. rifampicin
- alcohol
- Herbal medicines such as St John's wort (generally used for depression).

These medicines may be affected by Mizolam Tablet or may affect how well it works.

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

How to use Mizolam Tablet

- How much to use

Take Mizolam Tablet exactly as your doctor has prescribed.

Your doctor will tell you how many tablets to take.

If you are having Mizolam Tablet before a minor surgical procedure, this will be administered by a doctor or nurse.

The normal dosage for insomnia is 7.5mg to 15mg (one to two tablets).

In elderly and debilitated patients as well as patients with impaired liver or severely impaired kidney function, the recommended dose is 7.5mg (one tablet).

- When to use it

Mizolam Tablet should be taken immediately before going to bed, and swallowed whole with fluid.

Use as directed by your doctor or pharmacist.

- How long to use it

Mizolam Tablet is used for short term treatment of sleeping difficulty (insomnia) or as instructed by doctor. Generally the duration of treatment varies from a few days to a maximum of 2 weeks.

Continue taking Mizolam Tablet until your doctor tells you to stop.

- If you forget to use it

If you forget to take Mizolam Tablet and your sleep is all right, do not take a dose until the next evening. If you miss a dose and wake up to have it, you require 7 or 8 uninterrupted sleeps for the effects to wear off.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Mizolam Tablet. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

Symptoms of overdose may include:

- drowsiness
- ataxia (abnormal and uncoordinated movement)
- low blood pressure
- cardiorespiratory depression (loss of heart and lung functions)
- apnea (pauses in breathing while sleeping)
- coma

If you are not sure what to do, contact your doctor or pharmacist.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Mizolam Tablet.

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

- Things you must not do

Do not drive or operate machinery until you know how Mizolam Tablet affects you.

Mizolam Tablet can cause drowsiness, dizziness, lack of concentration, loss of memory in some people which may affect the alertness. Make sure you know how Mizolam Tablets will affect you before driving, operating machinery or doing something which may be dangerous if you are drowsy, dizzy and unable to concentrate.

Do not drink alcohol after taking Mizolam Tablet.

- Things to be careful of

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have received Mizolam Tablet.

In addition to the beneficial effects of Mizolam Tablet, it is possible that unwanted effects will occur during treatment, even when it is used as intended. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration

- headache, hangover feeling in the morning
- unpleasant dreams, tiredness
- blurred vision
- feeling sick with or without vomiting
- worse sleep once you stop treatment
- depression
- agitation, aggression, irritability
- older patients may be more likely to fall and suffer fractures

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

- sudden anxiety or excitation, abnormal behavior
- hallucinations or delusions, psychosis
- an allergic reaction – symptoms may include shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on the list.

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 Mizolam Tablet

- Storage

Mizolam Tablet must be kept in a cool dry place where the temperature stays below 30°C. They should be protected from light.

Mizolam Tablet given before a procedure will be kept at the clinic and given by a doctor.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

- What it looks like

Oval shape, yellow colour film coated tablet with “CCM” marking at one side and scored at another side.

- Ingredients

- Active ingredient
Midazolam maleate 7.5mg
- Inactive ingredients
 - Lactose monohydrate
 - Microcrystalline cellulose 200
 - Microcrystalline cellulose 102
 - Opadry II yellow
 - Sodium starch glycolate
 - Magnesium stearate

- MAL number: MAL12020012AZ

Manufacturer

UPHA PHARMACEUTICAL MFG.(M)
SDN BHD (53667-M)
Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan.

Product Registration Holder

CCM PHARMACEUTICALS SDN
BHD (27754-W)
Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan.

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02/11/2015

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