

Ranzepam

Diazepam Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ranzepam.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ranzepam against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Ranzepam is used for

Diazepam has sedative and muscle relaxant effects and is used to:

- treat anxiety (anxiety or tension associated with the normal stress of everyday life which usually does not require treatment with medicines)
- relax muscles

- treat symptoms such as trembling, confusion and anxiety associated with alcohol withdrawal
- treat panic attacks

Diazepam belongs to a group of medicines called benzodiazepines.

These medicines are thought to work by their action on brain chemicals.

Benzodiazepines are not recommended as the only treatment of severe mental illnesses and should not be used alone to treat depression.

Your doctor, however, may have prescribed it for another purpose.

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

In general, benzodiazepines such as Ranzepam should be taken for short periods only (around 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.

The use of benzodiazepines may lead to dependence on the medicine.

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

Before you take Ranzepam

When you must not take it

Do not take Ranzepam if you have an allergy to:

- any medicine containing diazepam
- any of the ingredients listed at the end of this leaflet

- any other benzodiazepine medicine

Some of the symptoms of an allergic reaction 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.

Do not take this medicine if:

- you have severe and chronic lung disease
- you have severe liver disease
- you have temporary stops in breathing during sleep (sleep apnoea)
- you suffer from severe muscle weakness known as myasthenia gravis
- you have drug or alcohol addiction (unless your doctor has prescribed it to help with relieving symptoms of alcohol withdrawal)
- if the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.
- if the packaging is torn or shows signs of tampering.

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

Do not give Ranzepam to children less than six months old.

Before you start to take it

Your doctor must know about all the following before you start to take diazepam:

1. **if you are pregnant or plan to become pregnant**

It is not known whether diazepam is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take diazepam when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

2. **if you are breast-feeding or plan to breast-feed**

Diazepam may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. Ranzepam is not recommended for use while breast-feeding.

3. **if you have any other health problems including:**

- liver, kidney or lung disease
- high or low blood pressure
- glaucoma (high pressure in the eye)
- depression, schizophrenia or other mental illness
- epilepsy (fits or convulsions)
- history of alcohol and drug abuse

4. **if you drink alcohol**

Alcohol may increase the effects of diazepam.

5. **if you are allergic to any other medicines, foods, dyes or preservatives**

6. **if you are intolerant of, or allergic to lactose. Ranzepam contains lactose.**

Taking other medicines

Tell your doctor or pharmacist 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 may interfere with Ranzepam. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- medicines used to treat depression
- medicines to control fits

- medicines for allergies or colds (e.g. antihistamines)
- pain relievers
- muscle relaxants
- cimetidine and omeprazole (medicines used to treat ulcers)
- disulfiram (a medicine used in the treatment of alcoholism)
- cisapride (a medicine used to treat gastric reflex)
- ketoconazole (a medicine used to treat fungal infections).

These medicines may be affected by diazepam or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Ranzepam.

If you are taking any other medications, check with your doctor before you start to take Ranzepam.

How to take Ranzepam

How much to take

Take Ranzepam exactly as your doctor has prescribed.

Your doctor will tell you how many Ranzepam tablets to take each day.

The dose of diazepam varies from person to person depending on age and the condition being treated. The usual adult dose is between 5 and 40 mg daily. Children, elderly and very ill patients may need to take less.

How to take it

Swallow Ranzepam tablets with a full glass of water.

When to take it

Diazepam can be taken up to three times a day. Your doctor will tell you how much you need to take. The tablets can be taken with or without food.

How long to take it

Usually, diazepam should be taken for short periods only (for example, for 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Continue taking Ranzepam until your doctor tells you to stop.

If you forget to take 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.

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

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

This may increase the chance of you getting an unwanted side effect.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 diazepam.

Do this even if there are no signs of discomfort or poisoning.

Also report any other medicine or alcohol which has been taken.

You may need urgent medical attention.

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

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

While you are taking Ranzepam

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking diazepam.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

If you become pregnant while you are taking Ranzepam, tell your doctor immediately.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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.

Always discuss with your doctor any problems or difficulties during or after taking Ranzepam.

Things you must not do

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

Diazepam may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to diazepam before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert. Even if you take this medicine at night, you may still be drowsy or dizzy the next day.

Do not take diazepam for a longer time than your doctor has prescribed.

Diazepam should be taken for short periods only (for example, 2 to 4 weeks), unless advised by your doctor.

Do not stop taking your medicine or lower the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects. 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.

Do not suddenly stop taking diazepam if you suffer from epilepsy. Stopping this medicine suddenly may make your epilepsy worse.

Do not take Ranzepam to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

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

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Ranzepam.

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 while you are taking Ranzepam.

This medicine helps most people with anxiety but it may have unwanted side effects in a few people. All medicines may have side effects. Sometimes they are serious, most of the time they are not. Some side effects may require medical treatment.

If you are elderly, unwell or taking other medicines, you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams

The above list includes the more common side effects of diazepam. They are usually mild and may disappear if the dose is reduced.

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

- sudden anxiety or excitation
- restlessness, agitation, irritability, anger, abnormal behaviour
- hallucinations or delusions
- severe sleep disturbances

- difficulties in breathing or choking or coughing

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

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 this list.

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.

After using Ranzepam

Storage

Keep your tablets in the original packaging until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Keep Ranzepam in a cool dry place, protected from light and where the temperature stays below 25°C.

Do not store diazepam, or any other medicines in a 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 Ranzepam where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Ranzepam looks like

- Ranzepam 2 mg tablets: white to off-white round, biconvex uncoated tablets debossed with '2' on one side and plain on the other side; available in blister packs of 50 tablets.
- Ranzepam 5 mg tablets: white to off-white round, flat bevelled edged uncoated tablets debossed with '5' and a scoreline on one side and plain on the other side; available in blister packs of 50 tablets.

Ingredients

Ranzepam tablets contain 2 mg or 5 mg of diazepam as the active ingredient.

They also contain the following inactive ingredients:

- lactose
- maize starch
- silica - colloidal anhydrous
- magnesium stearate
- purified talc.

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Ranbaxy Australia Pty Ltd
9-13 Waterloo Road
Macquarie Park NSW 2113
Australia

Australian Registration Numbers

- Ranzepam 2 mg tablets: AUST R 134589.
- Ranzepam 5 mg tablets: AUST R 134473.

This leaflet was prepared in March 2014.