

FRISIUM(R)

clobazam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FRISIUM. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What FRISIUM is used for

FRISIUM is used for anxiety and sleep disturbances associated with anxiety. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

Your doctor, however, may prescribe FRISIUM for another purpose. Ask your doctor if you have any questions about why FRISIUM has been prescribed for you.

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

In general, benzodiazepines such as FRISIUM, should be taken for short periods only (up to one month).

Continuous long term use is not recommended unless advised by your doctor. The prolonged use of benzodiazepines may lead to dependence on the medicine.

FRISIUM is not recommended for use in children.

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

Before you take FRISIUM

When you must not take it

Do not take FRISIUM if:

1. You have an allergy to FRISIUM (clobazam) or any other medicine from the benzodiazepine group of medicines or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swelling.
2. **You have severe or chronic lung disease.**
3. **You have a history of drug or alcohol abuse.**
4. **You suffer from severe muscle weakness known as myasthenia gravis.**
5. **You have sleep apnoea syndrome where you snore heavily and stop breathing during the night.**
6. **You have severely reduced liver function.**
7. **You are breastfeeding or plan to breast-feed**

FRISIUM may pass into the breast milk and cause drowsiness and/or feeding difficulties in the infant. FRISIUM is not recommended for use while breastfeeding.

Do not use FRISIUM if the packaging is torn or shows signs of tampering.

Do not use FRISIUM after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Before you start to take it

You must tell your doctor if:

1. **You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
2. **You are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of taking FRISIUM during pregnancy.

3. **You are breastfeeding or plan to breastfeed.**

FRISIUM is not recommended for use while breastfeeding.

4. **You have or have had any other medical conditions including:**

- * liver, kidney or lung disease
- * if you suffer from fits or convulsions (epilepsy)
- * if you have low blood pressure
- * if you have glaucoma (high pressure in the eye)
- * if you suffer from depression, psychosis or schizophrenia

5. You drink alcohol regularly.

Your tolerance to alcohol will be reduced and it will increase the effect of FRISIUM. Alcohol should be avoided during FRISIUM use.

If you have not told your doctor about any of the above, tell them before you take any FRISIUM.

Taking other medicines

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

Some medicines may interfere with FRISIUM. These include:

- * other sleeping tablets, sedatives or tranquillisers
- * medicines for depression
- * medicines for allergies, for example antihistamines or cold tablets
- * pain relievers
- * muscle relaxants
- * medicines to control fits

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

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking FRISIUM.

How to take FRISIUM

How much to take

The dose of FRISIUM may be different for each person. Your doctor will decide the right dose for you.

How to take it

Swallow the prescribed dose of FRISIUM tablet(s) with a glass of water.

How long to take it

Do not use FRISIUM for longer than your doctor has advised.

If you forget to take it

Take the dose as soon as you remember, and then go back to taking it as you would normally.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Australia: telephone 13 11 26, New Zealand: telephone 0800 POISON, 0800 764766) 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 FRISIUM. 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 take too much FRISIUM you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are using FRISIUM

Things you must do

Use FRISIUM exactly as your doctor has prescribed.

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

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

Tell your doctor if you feel FRISIUM is not helping your condition.

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.

Things you must not do

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

FRISIUM may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to FRISIUM before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Even if you take FRISIUM at night, you may still be drowsy or dizzy the next day.

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

Do not stop taking FRISIUM or change the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects. You and your doctor will slowly reduce your dose of FRISIUM before you can stop taking it completely.

Do not suddenly stop taking FRISIUM if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not use this medicine to treat any other complaints unless your doctor recommends it.

Do not give FRISIUM to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using FRISIUM.

Check with your doctor as soon as possible if you have any problems while taking FRISIUM, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, FRISIUM can cause some side effects. If they occur, most are likely to be minor and temporary.

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

These are the more common side effects of FRISIUM:

- * drowsiness, tiredness
- * dizziness, unsteadiness, tremor, sweating, muscle aches, spasms or weakness
- * loss of memory, confusion, lack of concentration
- * depression
- * headache, hangover feeling in the morning
- * nausea, vomiting, diarrhoea, constipation
- * weight gain
- * dry mouth or slurred speech
- * blurred vision
- * skin rash
- * changes in sex drive

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

- * sudden anxiety or excitation
- * hallucinations or delusions
- * severe sleep disturbances
- * irritability, aggressiveness
- * breathing difficulties

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

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking FRISIUM.

Ask your doctor or pharmacist if you don't 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 FRISIUM

Storage

Keep your tablets in their blister pack until it is time to take them.

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

Keep FRISIUM in a cool dry place where the temperature stays below 30 degrees C. Do not store it, or any other medicines, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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 FRISIUM or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

FRISIUM tablets are white, round and scored.

Ingredients

FRISIUM tablets do not contain sucrose, tartrazine or any other azo dyes.

FRISIUM tablets contain 10mg of clobazam as the active ingredient. Inactive ingredients include: maize starch, lactose, talc, colloidal silica and magnesium stearate.

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