

## 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 this medicine against the benefits they expect it will 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

#### Adults

Used to treat 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.

#### Children

Used along with other medicines to treat partial refractory and Lennox-Gastaut epilepsy (fits) in children 4 years of age or older.

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.

Your doctor, however, may prescribe Frisium for another purpose.

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

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 you have:**

- severe or chronic lung disease
- a history of drug or alcohol abuse
- severe muscle weakness known as myasthenia gravis
- sleep apnoea syndrome where you snore heavily and stop breathing during the night
- severely reduced liver function.

**Do not take Frisium (clobazam) if you are allergic to it or any other medicine from the benzodiazepine group of medicines or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

**Do not give Frisium to a child or adolescent for the treatment of anxiety or sleep disorders.**

**Do not take Frisium if you are pregnant or if you intend to become pregnant.**

**Do not take it if you are breast-feeding or planning to breast-feed.**

Frisium passes into the breast milk and may cause drowsiness and/or feeding difficulties in the infant.

**Do not use it 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.

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

*Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to:**

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

**Tell your doctor if you are pregnant or plan to become pregnant.**

Like most medicines of this kind, Frisium is not recommended in pregnancy unless the expected benefits outweigh possible risks. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

**Tell your doctor if you are breast-feeding or planning to breast-feed.**

Frisium passes into breast milk and is not recommended for use while breast-feeding.

**Tell your doctor if you have or have had any other medical conditions, especially the following:**

- liver, kidney or lung disease
- fits or convulsions (epilepsy)
- low blood pressure
- pre-existing muscle weakness
- ataxia (unsteadiness when walking)
- addiction to drugs or medicines
- glaucoma (high pressure in the eye)
- depression, psychosis or schizophrenia
- if 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 any that you buy without a prescription from your pharmacy, supermarket or health food store.**

Some medicines may interfere with the absorption of Frisium. These include:

- other sleeping tablets, sedatives or tranquillisers
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- anticholinergics (medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease)
- alcohol, (ethanol), contained in some medicines eg cough syrups

- medicines used to treat reflux or upset stomach, such as omeprazole
- medicines for depression
- medicines for allergies, for example antihistamines or cold tablets
- pain relievers, such as opioids or narcotic analgesics
- 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 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.

**Ask your doctor if you are unsure of the correct dose for you.**

He/she will tell you exactly how much to take.

**Follow the instructions you are given.**

If you take the wrong dose, Frisium may not work as well and your problem may not improve.

#### How to take it

**Swallow the prescribed dose of Frisium tablet(s) with a full glass of water.**

#### When to take it

**Take Frisium at about the same time each day preferably in the evening.**

Taking tablets at the same time each day will have the best effects. It will also help you remember when to take the tablets.

**If you are not sure when to take it, ask your doctor.**

#### How long to take it

**Do not use Frisium for longer than your doctor has advised.**

**Ask your doctor if you are not sure how long to take the medicine for.**

#### If you forget to take it

**Do not try to make up for missed doses by taking more than one dose at a time.**

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

**If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.**

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

**If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.**

**If you are not sure what to do, ask your doctor.**

**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 telephone 13 11 26, or go to Accident and Emergency at**

your nearest hospital, if you think 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 will probably feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

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### While you are taking it

#### *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 are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Frisium.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

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

#### *Things you must not do*

Do not take more than the recommended dose unless your doctor tells you to.

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

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Frisium, or lower the dosage, because you are feeling better, unless advised by your doctor.

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.

#### *Things to be careful of*

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.

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### Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine

against the benefits he/she expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

It helps most people but it may have unwanted side effects in a few people.

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

- 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.

These are mild side effects of this medicine.

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

- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- sudden anxiety or excitation
- hallucinations or delusions
- severe sleep disturbances
- irritability, aggressiveness
- breathing difficulties.

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

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.

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.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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### After taking Frisium

If you have any queries about any aspects of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

#### *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 the medicine in a cool dry place where the temperature stays below 30°C.

Do not store it, or any other medicines, in a bathroom, near a sink or on a window sill.

Do not leave it in the car.

Heat and damp 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 that are left over.

Return any unused medicine to your pharmacist.

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### Product description

#### *What it looks like*

Frisium tablets are white, round and scored. Frisium tablets can be halved if a lower dose is recommended by your doctor.

Frisium is available in packs of 50.

#### *Ingredients*

Active ingredient:

10 mg clobazam per tablet

Inactive Ingredients:

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

Frisium does not contain sucrose, tartrazine or any other azo dyes.

#### *Manufacturer/Sponsor*

Frisium is supplied in Australia by:

sanofi-aventis australia pty ltd  
12-24 Talavera Road  
Macquarie Park NSW 2113

Australian registration number:  
AUST R: 12400

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