

Frisium®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Frisium?

Frisium contains the active ingredient clobazam. Frisium is used to treat anxiety and sleep disturbances associated with anxiety in adults, and used along with other medicines to treat partial refractory and Lennox-Gastaut epilepsy (fits) in children 4 years of age or older. For more information, see Section [1. Why am I using Frisium?](#) in the full CMI.

2. What should I know before I use Frisium?

Do not use if you have ever had an allergic reaction to Frisium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are

breastfeeding. For more information, see Section [2. What should I know before I use Frisium?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Frisium and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Frisium?

- Swallow the prescribed dose of Frisium tablet(s) with a full glass of water.
- The dose of Frisium may be different for each person. Your doctor will decide the right dose for you.

More instructions can be found in Section [4. How do I use Frisium?](#) in the full CMI.

5. What should I know while using Frisium?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Frisium.• If you become pregnant while you are taking this medicine, tell your doctor immediately.
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<p>Things you should not do</p>	<ul style="list-style-type: none"> ● 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 suddenly stop taking Frisium if you suffer from epilepsy.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● 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.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Alcohol should be avoided during Frisium use. ● Your tolerance to alcohol will be reduced and it will increase the effect of Frisium.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep the medicine in a cool dry place where the

	temperature stays below 30°C.
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For more information, see Section [5. What should I know while using Frisium?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include drowsiness, tiredness, dizziness, unsteadiness, tremor, sweating, muscle aches, spasms or weakness, nausea, vomiting, diarrhoea, constipation, weight gain, loss of memory, confusion, lack of concentration, depression, headache, hangover feeling in the morning, dry mouth or slurred speech, blurred vision, skin rash and changes in sex drive. Serious side effects include Frisium dependence, severe blisters and bleeding on the face and genitals, sudden anxiety or excitation, feeling suicidal, suicidal thoughts or behaviour, hallucinations or delusions, severe sleep disturbances, irritability, aggressiveness and breathing difficulties. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Frisium®

Active ingredient: *clobazam*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Frisium. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Frisium.**

Where to find information in this leaflet:

- [1. Why am I using Frisium?](#)
- [2. What should I know before I use Frisium?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Frisium?](#)
- [5. What should I know while using Frisium?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Frisium?

Frisium contains the active ingredient clobazam. 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.

Adults

Frisium is 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

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

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.

2. What should I know before I use Frisium?

Warnings

Do not use Frisium if:

- you are allergic to clobazam, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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

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.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

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

Pregnancy and breastfeeding

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

Benzodiazepines including Frisium cross the placenta and may cause reduced muscle strength, breathing difficulties, hypothermia (a drop in body temperature) and feeding difficulties (signs and symptoms of so-called “floppy infant syndrome”) in the newborn infant with potentially fatal effects.

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. It is not recommended for use while breast-feeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with the absorption of Frisium and affect how it works.

- 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
- dietary supplements and recreational products
- medicines to control fits (including marijuana).

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.

The use of Frisium together with opioids increases the risk of drowsiness, difficulties breathing, coma and death.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Frisium.

4. How do I use 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.**
- Follow the instructions provided and use Frisium until your doctor tells you to stop.

- If you take the wrong dose, Frisium may not work as well and your problem may not improve.
- **Swallow the prescribed dose of Frisium tablet(s) with a full glass of water.**
- Frisium tablets can be halved if a lower dose is recommended by your doctor.

When to take Frisium

- **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 Frisium

- **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 use Frisium

Frisium should be used regularly at the same time each day. If you miss your dose at the usual time.

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 your next dose when you are meant to.

Do not take a double dose to make up for the dose you 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 use too much Frisium

If you think that you have used too much Frisium, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using Frisium?

Things you should 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.

All mentions of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your tolerance to alcohol will be reduced and it will increase the effect of Frisium.

Alcohol should be avoided during Frisium use.

Dependence and withdrawal

Frisium should only be used for short periods of time (2 to 4 weeks).

The use of benzodiazepines may lead to physical and psychological dependence and withdrawal syndrome when you stop taking the medicine.

If you stop taking Frisium suddenly you may experience the following withdrawal effects:

- depression
- nervousness
- difficulty in sleeping
- irritability
- sweating
- upset stomach/diarrhoea
- or the symptoms you are being treated for can come back worse than before

You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time. If you stop taking this medicine suddenly you may experience confusion, hallucinations,

shaking, faster heartbeat or fits. Withdrawal may also cause unusual behaviour including aggressive outbursts, excitement or depression with suicidal thoughts or actions.

Looking after your medicine

- 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.
- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unused medicine

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.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Body related:</p> <ul style="list-style-type: none">• drowsiness, tiredness• dizziness, unsteadiness, tremor, sweating, muscle aches, spasms or weakness• nausea, vomiting, diarrhoea, constipation• weight gain <p>Head related:</p> <ul style="list-style-type: none">• loss of memory, confusion, lack of concentration• depression	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● headache, hangover feeling in the morning ● dry mouth or slurred speech ● blurred vision <p>Skin related:</p> <ul style="list-style-type: none"> ● skin rash ● changes in sex drive 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Becoming dependent on Frisium ('physical or mental dependence') (especially in long term use) <p>Skin related:</p> <ul style="list-style-type: none"> ● Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals <p>Head related:</p> <ul style="list-style-type: none"> ● sudden anxiety or excitation 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • feeling suicidal and/or suicidal thoughts or behaviour • hallucinations or delusions • severe sleep disturbances • irritability, aggressiveness <p>Breathing related:</p> <ul style="list-style-type: none"> • breathing difficulties 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Frisium contains

Active ingredient (main ingredient)	Clobazam 10 mg per tablet
Other ingredients (inactive ingredients)	Maize starch Lactose monohydrate Purified talc Colloidal silica Magnesium stearate
Potential allergens	Lactose as sugars

Do not take this medicine if you are allergic to any of these ingredients.

What Frisium looks like

Frisium tablets are white, round and scored (Aust R 12400). Frisium is available in packs of 50.

Who distributes Frisium

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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