

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

FRISIUM® (clobazam tablets)

Read this carefully before you or your child start taking FRISIUM and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about FRISIUM.

What is FRISIUM used for?

FRISIUM is used as add-on therapy in patients whose epilepsy is not well controlled on their current antiepileptic drugs.

How does FRISIUM work?

FRISIUM belongs to the family of medicines called anticonvulsants. It acts in the brain to block the spread of seizure activity.

What are the ingredients in FRISIUM?

Medicinal ingredients: clobazam

Non-medicinal ingredients: colloidal silicon dioxide, lactose, magnesium stearate, starch (corn) and talc

FRISIUM comes in the following dosage forms:

Tablets, 10 mg

Do not use FRISIUM if you or your child:

- are allergic to the active ingredient clobazam or any of the other ingredients
- have been diagnosed with myasthenia gravis
- have narrow angle glaucoma (increased pressure in your eye)
- have any history of drug or alcohol dependence
- have severe difficulty breathing
- have sleep apnea (pauses in breathing during sleep)
- have severe liver problems
- are in the 1st trimester (first 3 months) of pregnancy. Avoid becoming pregnant while taking FRISIUM. Effective birth control methods must be used, Tell your healthcare professional right away if you become pregnant during treatment or plan to get pregnant.
- are breastfeeding. If you are breastfeeding, you should stop before starting treatment with FRISIUM since clobazam passes into breast milk.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child take FRISIUM. Talk about any health conditions or problems you

or your child may have, including if you:

- Have ever had a rash or unusual reaction while taking clobazam or any other antiepileptic drug.
- Are over the age of 65 or debilitated (in a weakened state)
- Have been diagnosed with decreased mental function due to a medical disease
- Use alcohol or drugs. Do not drink alcohol while you are taking FRISIUM.
- Have a history of drug or alcohol abuse. If you are dependent on drugs or alcohol, FRISIUM may increase your dependence.
- Have a history of mental illness, depression, and/or suicide attempts. FRISIUM increases the risk of suicidal thoughts or worsening of depression.
- Have kidney or liver problems. Your healthcare professional may need to adjust the dose.
- Have breathing problems.
- Have muscle weakness and/or spinal /cerebellar ataxia (sudden uncoordinated movements)
- Are pregnant or planning to become pregnant. FRISIUM is **not** to be used in the first trimester of pregnancy and must only be taken in the later stages if your healthcare professional tells you to.
 - If you become pregnant while taking FRISIUM, talk to your healthcare professional about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy. You can enroll in this registry by calling 1-888-233-2334. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>.
- Are in labour. Taking FRISIUM immediately before or during childbirth may have an effect on the newborn.
- Have difficulty forming new memories (anterograde amnesia). Anterograde amnesia is known to occur even if antiepileptics are used in the normal dose range, but especially at higher dose levels. Amnesia effects may be associated with inappropriate behaviour.
- Have been taking FRISIUM for a long time. It may not work as well as it used to.
- Are taking birth control.
 - FRISIUM may make hormonal birth control such as “the pill” less effective.
 - Use other forms of safe and effective birth control when taking FRISIUM.
 - You need to use other forms of birth control until the end of your menstrual cycle after stopping treatment.

Other warnings you should know about:

- **Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis:** FRISIUM can cause serious skin reactions that can spread to your mouth, lips, face, hands, trunk, arms and legs. These conditions are life-threatening. Stop taking FRISIUM and contact your healthcare professional immediately if you or your child gets a rash or any serious skin reactions. This includes skin peeling, itch, redness, and blisters of the lips, eyes, mouth, nasal passages or genitals. Often, skin reactions occur after 1 to 2 weeks of fever, or other symptoms such as sore throat, fatigue, chills, and headache.

- **Driving and using machines:** Before doing tasks that require special attention, wait until you know how you respond as FRISIUM can cause drowsiness, dizziness and muscle weakness.
- Do not suddenly stop taking FRISIUM. Always follow your healthcare professional's instructions. Stopping this drug quickly may lead to an increase in seizure activity or withdrawal symptoms, such as headaches, trouble sleeping, anxiety, confusion and irritability.

DURING treatment with FRISIUM, tell your healthcare professional if you or your child develops:

- Thoughts of suicide or self-harm

Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FRISIUM:

- Hormonal birth control (such as “the pill”).
- Other antiepileptic drugs (such as carbamazepine, phenytoin, valproate, phenobarbital).
- Drugs used to treat fungal infections (such as fluconazole).
- Antidepressant medications (such as fluvoxamine).
- Ticlopidine, used to prevent blood clots and help prevent strokes and heart attacks.
- Omeprazole used to reduce stomach acid.
- Other drugs that affect your nervous system (such as antipsychotics, antihistamines that make you drowsy, anesthetics, other sedatives such as sleeping pills).
- Lithium used to treat bipolar disease.
- Narcotics (strong pain medications). Increased addiction can occur.
- Muscle relaxants and nitrous oxide (products often used in surgery or during dental procedures). FRISIUM can prolong the effects.
- Alcohol.

How to take FRISIUM:

FRISIUM is a tablet to be taken by mouth. The tablets can be taken whole, or broken in half along the score line.

Always follow your healthcare professional's instructions. Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your healthcare professional.

Do not stop taking FRISIUM without talking to your healthcare professional. Stopping a seizure medicine suddenly can cause serious problems, including seizures that will not stop. Your healthcare professional will tell you if and when you or your child can stop taking this medicine.

If the daily dose of FRISIUM is to be divided, the higher portion should be taken at night (up to 30 mg may be taken as a single dose at night).

If you or your child are taking FRISIUM for an extended period of time, your healthcare professional will perform regular blood tests for liver, kidney and thyroid function.

Usual dose:

Adults: The starting dose is 5-15 mg/day increasing gradually to a maximum daily dose of 80 mg if needed.

Children from 2 to 16 years: The starting dose is 5 mg/day, which can be increased at 5 day intervals to a maximum daily dose of 40 mg/day if needed.

Infants <2 years: The dose is based on body weight and will be determined by your healthcare professional.

Elderly patients (>65 years), patients with kidney, liver or breathing problems, muscle weakness or dizziness and unsteadiness when walking (spinal or cerebellar ataxia) and patients who are poor metabolizers of antiepileptic drugs (CYP2C19 poor metabolizers) may require lower doses.

Overdose:

If you think you or your child have taken too much FRISIUM, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you or your child have taken too large a dose of FRISIUM, you may become drowsy, confused, and sluggish. You may have trouble walking, reacting, breathing, staying awake, or have low blood pressure. A coma or death is possible. Taking alcohol or other drugs that affect your nervous system at the same time as FRISIUM increases the risk of death. When too much FRISIUM wears off, you could be excited and jittery.

Missed Dose:

If you or your child misses a dose of FRISIUM, take it as soon as you remember. If you are close to your next dose, just take your next dose, without making up for the missed dose. Do not take 2 doses at the same time.

What are possible side effects from using FRISIUM?

These are not all the possible side effects you or your child may feel when taking FRISIUM. If you or your child experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

The most common side effects associated with the use of FRISIUM are:

- Sleepiness/drowsiness, feeling tired/fatigue
- Dizziness

Common side effects include:

- Loss of coordination
- Nervousness
- Blurred vision
- Weight increase

Other side effects include:

- Headache
- Shakiness, tremor
- Slowed reaction time, muscle weakness
- Confusion, disorientation, trouble speaking, trance, diminished responsiveness
- Constipation, changes in appetite, nausea, vomiting, bloating, dry mouth, trouble swallowing
- Drooling
- Difficulty passing urine, bladder infection
- Fever
- Lower than normal body temperature
- Nasal congestion (blocked nose)
- Rash

The following side effects occur after taking FRISIUM for a long time or at high doses, but they can be reversed: Slowed or slurred speech, unsteady walking and other muscle functions, vision problems, weight gain, and loss of sexual desire.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Difficulty falling asleep or staying asleep		√	
Psychiatric Disorders (symptoms like irritability, mood swings, restlessness, anxiety, aggressiveness, fits of rage, delusions, changes in thinking)		√	
Nightmares		√	
Hallucinations: See and hear things that are not there		√	
Thoughts of suicide or self-harm			√
Frequent Muscle Spasms		√	
Pneumonia/Aspiration		√	

Pneumonia, Bronchitis (symptoms like cough, fever, difficulty breathing, chills)			
RARE			
Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): Any combination of itchy skin rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages, or genitals. You may also get fever, sore throat, fatigue, chills, headache, cough, body aches or joint pain.			√
VERY RARE			
Allergic reactions: <ul style="list-style-type: none"> • Swelling of lips, eyelids, face, throat, or mouth, accompanied by difficulty in breathing, speaking or swallowing (signs of anaphylactic reactions and angioedema) • Skin rash, fever, swollen glands (swelling of the lymph nodes), and pain in the muscles and joints (signs of hypersensitivity reactions) • Red blotchy rash mainly on face which may be accompanied by fatigue, fever, nausea, loss of appetite (signs of systemic lupus) 			√
UNKNOWN			
Altered numbers and types of blood cells (symptoms like unexplained tiredness, weakness, shortness of breath, and sometimes, feeling like you are going to pass out, increased bruising, nosebleeds, sore throats, or infections)		√ You should tell your healthcare professional who may want to perform a blood test	

Anterograde Amnesia (symptoms like loss of the ability to create new memories, inappropriate behaviour)		√	
Respiratory depression (symptoms like shallow slow, weak breathing)			√

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

FRISIUM tablets should be stored in their original containers at room temperature, between 15-30°C.

Keep out of reach and sight of children.

If you want more information about FRISIUM:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://hc-sc.gc.ca/index-eng.php) (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website, www.lundbeck.com, or by calling +1 866 880 4636.

This information is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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