

FRISIUM[®] TABLET

Clobazam (10mg)

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What Frisium is used for

Frisium can be used for:

- Prolonged or sudden severe anxiety
- Epilepsy (fits) not adequately stabilised as adjunctive therapy
- Depression or anxiety associated with depression
- Mental illness such as schizophrenia or other psychotic illnesses (in combination with other treatments)

How Frisium works

Frisium contains a medicine called Clobazam. This belongs to a group of medicines called benzodiazepines. It works by having a calming effect on the brain.

Before you use Frisium

- When you must not use it

- You are allergic (hypersensitive) to clobazam, other benzodiazepine medicines or any of the other ingredients of Frisium (listed in ingredients below)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have ever had problems with medicines, drugs or alcohol dependence in the past
- You suffer from an illness that causes muscle weakness (called 'myasthenia gravis')
- If you are in first three months of pregnancy or breast-feeding.
- You have severe liver problems

- You have severe breathing problems
- You stop breathing for short periods during sleep (called 'sleep apnoea syndrome')
- Your child is under 6 years of age.
- You have problems of sugar intolerance or absorption.

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Frisium.

- Before you start to use it

Check with your doctor or pharmacist before taking your medicine if:

- You have problems with controlling your movements (called 'spinal or cerebellar ataxia')
- You have kidney problems
- You have liver problems
- If you have depression, anxiety.

Suicidal thoughts: Some individuals (particularly in children and adolescent) have experienced suicidal thoughts while taking medicines containing clobazam. If you start experiencing thoughts of suicide or harm towards yourself please tell your doctor immediately.

Dependence, tolerance and withdrawal:

It is possible for you to become dependent on Frisium if you take it for long periods of time or in high dose, particularly if you have a history of heavy alcohol or medicinal use. This means that you may feel that you need to continue treatment in order to feel well (known as psychological dependence).

If you suddenly stop taking Frisium you may experience worsening of the symptoms you were originally being treated for, as well as mood changes, anxiety, sleep disturbance or restlessness.

This is known as withdrawal and can be avoided by slowly reducing your dose. If you are worried about dependence or withdrawal please talk to your doctor.

If you take Frisium for long periods of time for treatment of epilepsy it is possible that you may become tolerant to it, meaning that it will not be as effective as it was when you first started taking it. If you feel that Frisium is no longer helping to control your symptoms, please talk to your doctor.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Frisium.

- Taking other medicines

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

In particular, tell your doctor if you are taking any of the following:

- Medicines for epilepsy (such as phenytoin, carbamazepine, stiripentol or valproic acid)
- Medicines for depression (such as fluvoxamine or paroxetine)
- Medicines for severe mental illness called 'antipsychotics' (such as pimozide)
- Narcotic painkillers
- Sleeping tablets
- Tranquilisers
- Antihistamines that make you sleepy
- Cimetidine - used to treat ulcers and heartburn
- Erythromycin-used to treat infections
- Beta blockers (such as nebivolol)
- muscle relaxants
- Omeprazole - used to treat the symptoms of acid reflux such as heartburn or acid regurgitation.
- Ticlopidine – a blood thinning medication used in people with an increased risk of stroke
- Fluconazole - used in the treatment of fungal conditions
- Dextromethorphan - used to relieve dry, irritating coughs

If you are not sure if any of the above apply to you talk to your doctor or pharmacist.

How to use Frisium

- How much to use

Adults

- The usual dose is 5mg to 80mg each day. If the dose is spread throughout the day, the larger portion should be taken in the evening.
- Your doctor may increase or lower your dose to suit you.

Children (from 6 years of age)

- The usual start dose is 5mg daily. A maintenance dose of 0.3 to 1.0 mg/kg daily is usually sufficient.

Elderly

- The usual dose for anxiety is 10mg to 15mg each day.

- When to use it

Take Frisium tablets at about the same time each day unless your doctor tells you otherwise.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the medicine.

Swallow the tablets whole, or crushed and mixed in applesauce. The tablets can be divided into equal halves of 5mg. Frisium can be taken with or without food.

If you are not sure when to consume it, ask your doctor or pharmacist.

- How long to use it

The duration of the treatment must be as short as possible. The doctor should assess your condition no more than two weeks for tension, agitation and anxiety treatment and no more than 4 weeks for epilepsy treatment after the start of treatment. The overall duration of treatments must not exceed 8 to 12 weeks. Your doctor may prolong your treatment period depends on your condition.

- If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you take more Frisium than you should, tell your doctor or go to your

nearest hospital casualty department straight away. Do not drive yourself, because you may start to feel sleepy. Remember to take with you any tablets that are left and the pack. The following effects may happen: drowsiness, sleepiness, lack of voluntary muscle movements, breathing difficulty, low blood pressure, and rarely coma.

While you are using it

- Things you must do

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

Pregnancy and breast-feeding

Frisium must not be taken in the first trimester of pregnancy. Use of clobazam before (especially third trimester) or during childbirth can result in the occurrence of breathing difficulty (including respiratory distress and interrupted breathing) which may be associated with other disorders such as sedation, agitation, tremor signs, abnormally low body temperature, low muscle tone and feeding difficulties in the newborn (signs and symptoms of the so-called 'floppy infant syndrome'). Prolonged use of Frisium in the later stages of pregnancy can lead to habituation and dependence in the unborn child and a withdrawal syndrome in the newborn infant. Appropriate monitoring of the newborn in the postnatal period is recommended.

Frisium must not be taken during breastfeeding because the active substance clobazam passes into breast milk.

- Things you must not do

- 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 change the dosage, without checking with your doctor.

- Do not drink alcohol while taking Frisium.

- Things to be careful of

Driving and using machines

You may feel sleepy or have concentration or memory problems after taking this medicine. If this happens, do not drive or use any tools or machines.

Side Effect

Anaphylaxis (severe allergic reaction) and angioedema (severe facial swelling) which can occur as early as the first time the product is taken.

Complex sleep – related behaviors which may include sleep driving, making phone calls, preparing and eating food while asleep.

Frisium should be discontinued at the first sign of rash, unless the rash is clearly not related to the medicine.

Like all medicines, Frisium can cause side effects, although not everybody gets them.

Do not be alarmed by this list of possible side effects. You may possibly not facing any of these.

Tell your doctor immediately if you:

- Feeling restless, have difficulty sleeping or nightmares
- Feeling irritable or anxious
- Being aggressive
- Shaking fingers
- Believing things which are not true (delusions)
- Sensing things which are not there (hallucinations)
- Feeling suicidal

These side effects are more likely to happen in elderly people and children.

The following side effects may happen:

- Feeling sleepy or dizzy
 - Dry mouth, constipation
 - Reduced appetite, feeling sick
- Other side-effects include:
- Severe skin reactions

- Headache
- Breathing problems
- Loss of memory, confusion
- Muscle weakness
- Problems walking or other movement problems
- Becoming dependent on Frisium (also called 'physical or mental' dependence)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Frisium

- Storage

- Keep out of the reach and sight of children.
- Do not use Frisium after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Do not store above 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

The tablets are round, biconvex, white tablets with score-line on one side. Frisium is presented in a blister pack of 100 tablets.

- Ingredients:

- Active ingredient: clobazam
- Inactive ingredients: lactose, maize starch, colloidal anhydrous silica, talc, and magnesium stearate.

- MAL Numbers:

MAL19861330AZ

Manufacturer

Sanofi Winthrop Industrie
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Product Registration Holder

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