

**PACKAGE LEAFLET:
INFORMATION FOR THE USER
Frisium®10 mg Tablets
Clobazam**

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Frisium is and what it is used for
2. What you need to know before you take Frisium
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1. WHAT FRISIUM IS AND WHAT IT IS USED FOR

Frisium contains a medicine called Clobazam. This belongs to a group of medicines called benzodiazepines. Frisium can be used for:

- Severe anxiety over a short time
- Epilepsy (fits) over a longer time

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FRISIUM

Do not take Frisium if:

- You are allergic (hypersensitive) to clobazam, other benzodiazepine medicines or any of the other ingredients of Frisium (see section 6: Further Information) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You are breast-feeding
- You suffer from pre-existing muscle weakness or an illness that causes muscle weakness (called 'myasthenia gravis')
- You have liver problems
- You have breathing problems
- You stop breathing for short periods during sleep (called 'sleep apnoea syndrome')
- You suffer from depression, as this may lead to suicidal thoughts.
- The patient is under 6 years old

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. Use of Frisium may lead to a physical addiction. Stopping Frisium suddenly may lead to side effects. Dependence on Frisium may occur. Extended use of Frisium, will lessen the effect it has on your symptoms.

Take special care with Frisium

Check with your doctor or pharmacist before taking your medicine

- If you have problems with controlling your movements (called 'spinal or cerebellar ataxia')
- If you have depression
- If you have delusions (believing things which are not true) or hallucinations (sensing things which are not there)
- If you have kidney problems
- If you have ever become dependent upon another drug or alcohol
- If you have a behavioural disorder
- If you have breathing difficulties
- If you are over 65. This is due to the increased sensitivity to adverse reactions in the elderly such as drowsiness, dizziness and muscle weakness. There is also an increased risk of fall that may result in serious injury.
- Before taking any non-medicinal products containing cannabidiol, as it may increase the side effects of clobazam
- If you are consuming any medicinal products containing cannabidiol, as it may increase the side effects of clobazam

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

Warnings and Precautions

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice. (see section 4). There have been very rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Frisium. Symptoms of which may include: flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking this medicine and inform your doctor straight away (see Section 4).

Taking Frisium with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Frisium can affect the way some other medicines work. Also some medicines can affect the way Frisium works.

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 Monoamine Oxidase Inhibitors (MAOIs) or tricyclic anti-depressants - such as trazodone or Selective Serotonin Re-uptake Inhibitors (SSRIs) such as fluvoxamine or paroxetine)
- Medicines for severe mental illness called 'antipsychotics' (such as chlorpromazine, haloperidol, clozapine and pimozide)
- Painkillers (such as medicines containing codeine, dihydrocodeine or morphine)
- Sleeping tablets (such as zolpidem)

- Tranquilisers (such as diazepam, temazepam or lorazepam)
- Muscle relaxants (such as baclofen)
- Antihistamines that make you sleepy (such as chlorphenamine, promethazine or diphenhydramine)
- Lithium - used for a mental illness called 'manic-depressive illness' (mood changes between a state of high excitability or exaggerated emotions and depression)
- Cimetidine - used to treat ulcers and heartburn
- Dextromethorphan - used to relieve dry, irritating coughs.
- Nebivolol - medicine used to treat high blood pressure.
- Cannabidiol containing products (medicinal or non-medicinal products)
- Ticlopidine - an antiplatelet medication used to prevent blood clots
- Fluconazole - used in the treatment of fungal conditions
- Omeprazole - used to treat stomach conditions

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

Anaesthetics

If you are going to have an anaesthetic, tell your doctor or anaesthetist you are taking Frisium. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants to give you.

Taking Frisium with food and drink

- Do not drink alcohol while taking Frisium. This is because alcohol can change the way Frisium works
- Frisium may be taken with or without food.

Pregnancy and breast-feeding:

Do not take Frisium if you are:

- Breast-feeding. This is because it may pass into the mother's milk

Use of this medicine is not recommended during pregnancy and in women of childbearing potential not using contraception. If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to re-assess the need for treatment. Do not stop taking Frisium without talking to your doctor.

A large amount of data has not shown evidence of malformations associated with the use of benzodiazepines. However, some studies have shown a potentially increased risk of cleft lip and palate in newborn babies compared to that in the general population. Use of this medicine is not recommended during pregnancy.

Cleft lip and palate (sometimes called "harelip") is a deformation at birth caused by incomplete fusion of the palate and upper lip.

Reduced fetal movement and fetal heart rate variability may occur after taking Clobazam during the second and/or third trimester of pregnancy.

If Frisium is taken at the end of pregnancy, your baby may show drowsiness (sedation), muscle weakness (hypotonia or floppy infant syndrome), a drop in body temperature (hypothermia), difficulty feeding (problems suckling causing poor weight gain) and breathing problems (respiratory depression sometimes severe).

If taken regularly in late pregnancy, your baby may get withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Driving and using machines

You may feel sleepy or have concentration or memory problems after taking this medicine. You may also experience double vision or you may react more slowly to things. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Frisium

If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

This is because Frisium contains lactose.

3. HOW TO TAKE FRISIUM

Always take Frisium exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

Swallow the tablets whole, or crushed and mixed with apple sauce. The tablets can be divided into equal halves of 5mg. Frisium can be taken with or without food. If the tablets are crushed and mixed with apple sauce, the mixture should be used immediately.

- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor
- Keep taking Frisium until your doctor tells you to stop, this should not be longer than 4 weeks.
- Frisium is usually given for 2 to 4 weeks. After that, your doctor will decide whether you should keep taking this medicine
- The lowest dose possible should be used to control the symptoms.

Adults

- The usual dose for anxiety is 20 mg to 30 mg each day. This can be taken as two separate doses or as a single dose at night
- The usual starting dose for epilepsy is 10mg to 20mg each day
- Your doctor may increase your dose to up to 60 mg each day
- Your doctor may lower the dose to suit you

Children (over 6 years)

- The usual dose for epilepsy is 5 mg each day
- Your doctor may increase your child's dose up to 30 mg each day
- Your doctor may lower the dose to suit your child
- Frisium is not recommended to children under 6.

Elderly

- The usual dose for anxiety is 10 mg to 20 mg each day

If you take more Frisium than you should

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. This is so the doctor knows what you have taken.

If you forget to take Frisium

- 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 stop taking Frisium

Keep taking this medicine until your doctor tells you to stop. Do not stop taking Frisium just because you feel better

- When your doctor says that you can stop taking Frisium, you need to do this gradually. Your doctor will help you to do this.
- Stopping the tablets can make you feel stressed (anxiety), confused or depressed. You may also lose your appetite and have difficulty sleeping. Tell your doctor if this happens.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Frisium can cause side effects, although not everybody gets them. You may feel ill after taking the tablets, or notice unusual or unexpected symptoms. If this happens, tell your doctor.

Tell your doctor straight away if you have any of the following side effects:

- Feeling restless, have difficulty sleeping or nightmares
- Feeling irritable or anxious
- Believing things which are not true (delusions)
- Sensing things which are not there (hallucinations)
- Feeling suicidal
- Increased possibility of tripping or falling especially in elderly patients.
- Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.
- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'Toxic epidermal necrolysis' (TEN). Both Stevens Johnson Syndrome and TEN can be fatal.

If you get any of the above side effects, your doctor may decide that your treatment needs to be stopped. These side-effects are more likely to happen in elderly people and children. Prolonged use of Frisium may lead to a dependence on the drug.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

Very Common:

- Feeling sleepy or tired (especially at the start of treatment)

Common:

- Headache
- Loss of appetite, feeling sick
- Feeling dizzy or confused
- Dry mouth, constipation
- Feeling aggressive
- Shaking fingers
- Difficulty in concentrating, staying awake or alert
- Slurred or slow speech
- Depression

Uncommon:

- Loss of memory, confusion, or trouble remembering things
- Unusual or out of character behaviour
- Feeling anxious
- Skin rash
- Weight gain
- Double vision
- Loss of sexual drive

Not known:

- Breathing problems
- Hives
- Muscle spasms or involuntary movement
- Muscle weakness
- Reacting to things more slowly than usual
- Problems walking or other movement problems
- Rapid uncontrollable movement of the eyes
- Abnormally low body temperature (hypothermia)
- Feeling angry

If you take this medicine for a long time, you are more likely to get the following side effects: anxiety, confusion, depression, loss of appetite and difficulty sleeping.

Use of Frisium may lead to a physical addiction. Stopping Frisium suddenly may lead to side effects. Dependence on Frisium may occur. Talk to your doctor if you feel you have developed a dependence on Frisium Tablets.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FRISIUM

Keep out of the reach and sight of children.

- Do not use Frisium after the expiry date which is stated on the carton and foil after 'EXP'. The expiry date refers to the last day of that month.
- If your tablets go out of date take them to your pharmacist for safe disposal.
- Do not store above 25°C. Store in the original package.

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.

6. FURTHER INFORMATION

What Frisium contains

Each tablet contains 10 mg clobazam as active ingredient. They also contain the following other ingredients: Lactose monohydrate, Maize starch, Colloidal anhydrous silica, Talc, Magnesium stearate.

What Frisium looks like and contents of the pack

Round, biconvex, white tablet, with score line on both face, one face engraved with C and 10 on the other side of the score line.

Frisium 10 mg Tablets are available in a pack size of 100 blister packs.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in March 2025