

Frisium® 10 mg Tablets

(clobazam)

This product is available using the above name but will be referred to as **Frisium** throughout the following:

Patient Information Leaflet

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) Before you take Frisium
- 3) How to take Frisium
- 4) Possible side effects
- 5) How to store Frisium
- 6) Further information

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. It works by having a calming effect on the brain.

Frisium can be used for:

- Severe anxiety over a short time
- Epilepsy (fits) over a longer time
- Mental illness such as schizophrenia (in combination with other treatments)

2) 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 in the first three months of pregnancy or think you might be pregnant (see below under 'Pregnancy and breast-feeding' for more information)
- You are breast-feeding
- You have ever had problems with drug or alcohol dependence in the past
- You suffer from 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')
- The patient is under 3 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.

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')
- You have depression, irrational fears and obsessions
- You have delusions (believing things which are not true) or hallucinations (sensing things which are not there)
- You have kidney problems
- You have ever become dependent upon another drug or alcohol

A small number of people being treated with anti-epileptics such as clobazam have had thoughts of harming or killing themselves.

If at any time you have these thoughts, immediately contact 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 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 or valproic acid)
- Medicines for depression (such as MAOIs or tricyclic anti-depressants – such as trazodone)
- Medicines for severe mental illness called 'neuroleptics' (such as chlorpromazine, haloperidol and clozapine)
- 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

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 operation or be given 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
- Take your tablets with at least half a glass of water
- Do not chew the tablets

Pregnancy and breast-feeding:

Do not take Frisium if you are:

- In the first three months of pregnancy
- Breast-feeding. This is because it may pass into the mother's milk

Talk to your doctor before taking this medicine if you are pregnant, plan to get pregnant, or think you may be pregnant.

This is because Frisium is not recommended for use in pregnant women.

However, your doctor may give you this medicine during late pregnancy or during labour

- If this happens, there is a risk of having a baby with a low body temperature, floppiness, breathing or feeding problems
- If this medicine is taken regularly in late pregnancy, your baby may get withdrawal symptoms

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 with half a glass of water. Do not chew the tablets.

- 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
- Frisium is usually given for 2 to 4 weeks. After that, your doctor will decide whether you should keep taking this medicine

Adults

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

Children (6 years and above)

- The usual dose is 5mg each day

Elderly

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

When 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 may 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

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.

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.

The following side effects are more likely to happen at the start of treatment. They usually last for a short time.

- Feeling sleepy or dizzy
- Dry mouth, constipation
- Loss of appetite, feeling sick
- Shaking fingers

Other side-effects include:

- Headache
- Breathing problems
- Loss of memory, confusion
- Skin rash
- Muscle weakness
- Problems walking or other movement problems
- Being aggressive
- Reacting to things more slowly than usual
- Eye problems such as double vision
- Difficulty in staying awake or alert
- Becoming dependent on Frisium (also called 'physical or mental dependence').
- Weight gain
- Loss of sexual drive

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.

5) How to store Frisium

• Keep out of the sight and reach 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.
- If your tablets go out of date take them to your pharmacist for safe disposal.
- Do not store above 25°C.
- 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.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Further information

What Frisium contains

Each tablet contains 10mg of clobazam as the active ingredient. They also contain the following inactive ingredients: lactose monohydrate, maize starch, talc, colloidal anhydrous silica and magnesium stearate.

What Frisium looks like and contents of the pack

The tablets are white, round, plain on one side and 'CBZ' break line '10' on the other side.

Frisium is presented in a blister pack of 30 tablets.

Who makes and repackages your medicine?

PL 10383/1830 Frisium® 10mg Tablets

POM

Your medicine is manufactured by Sanofi Winthrop Industrie 6, Boulevard de l'Europe, 21800 Quetigny, France and is procured from within the EU and repackaged by the Product Licence holder: Primecrown Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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.

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