

PACKAGE LEAFLET: INFORMATION FOR THE USER

Frisium® 10mg Tablets

Clobazam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Frisium is and what it is used for
2. What you need to know before you take Frisium
3. How to take Frisium
4. Possible side effects
5. How to store Frisium
6. Contents of the pack and other 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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FRISIUM

Do not take Frisium if:

- X You are allergic (hypersensitive) to clobazam, other benzodiazepine medicines or any of the other ingredients of Frisium (see section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- X You are pregnant or are planning to have a baby (see below under 'Pregnancy, breast-feeding and fertility' for more information).
- X You are breast-feeding.
- X You have ever had problems with drugs or alcohol dependence in the past.
- X You suffer from an illness that causes muscle weakness (called 'myasthenia gravis').
- X You have liver problems.
- X You have breathing problems.
- X You stop breathing for short periods during sleep (called 'sleep apnoea syndrome').
- X 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Frisium 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. Alcohol should not be taken during treatment with Frisium as there is an increased risk of experiencing side effects.
- 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.
- You have difficulty digesting medicines. Some patients' livers may not metabolise (break down) medicines adequately. In these patients the medicine may remain in the body for a longer period of time. This may result in side effects. If you are known to poorly metabolise certain medicines, please speak to your doctor.
- You are taking any medicinal or non-medicinal products containing cannabidiol, as it may increase the side effects of clobazam.

Drowsiness, difficulties breathing, coma and death may occur if Frisium is taken together with opioids. Frisium and opioids should only be used concomitantly, when other treatment options are inadequate. Please tell your doctor about all opioid medicines you are taking and follow your doctor's dosage recommendations closely.

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).

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

Other medicines and Frisium

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.
- Omeprazole – used to treat stomach conditions.
- Ticlopidine – an antiplatelet medication used to prevent blood clots.
- Fluconazole – used in the treatment of fungal conditions.
- Dextromethorphan – used to relieve dry, irritating coughs.
- Nebivolol – used to treat high blood pressure.
- Cannabidiol-containing products (medicinal or non-medicinal products).

Concomitant use of Frisium and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Follow your doctor's dosage recommendations closely.

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.

Frisium with alcohol

Do not drink alcohol while taking Frisium. This is because there is increased risk of sleepiness and other side effects.

Pregnancy, breast-feeding and fertility

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 reassess the need for treatment. Do not stop taking Frisium without talking to your doctor.

A large amount of data has not shown evidence for 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.

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 or during childbirth, 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.

Do not take Frisium if you are breast-feeding or are planning to breast-feed. This is because it may pass into the mothers' milk.

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.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Frisium contains lactose

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

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 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 2-4 weeks. After that, your doctor will decide whether you should keep taking this medicine.

Adults

- The usual dose is 20-30mg each day. This can be taken as two separate doses or as a single dose at night.
- Your doctor may increase your dose to 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 10-20mg 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.

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:

Common side effects (may affect up to 1 in 10 people):

- Feeling irritable or restless

Uncommon side effects (may affect up to 1 in 100 people):

- Poor memory while taking Frisium (amnesia) or showing unusual behaviour
- Nightmares
- Feeling anxious
- Believing things which are not true (delusions)
- Increased possibility of tripping or falling, especially in elderly patients

Not known (frequency cannot be estimated from available data):

- Sleeping problems that get worse after taking this medicine
- Sensing things which are not there (hallucinations)
- Being less aware of your environment, especially in the elderly
- Feeling suicidal
- 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'.
- A 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 is something called 'Toxic Epidermal Necrolysis'.

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.

Very common side effects (may affect more than 1 in 10 people):

- Difficulty in staying awake or alert

Common side effects (may affect up to 1 in 10 people):

- Feeling sleepy or dizzy
- Feeling agitated or being aggressive
- Depression
- Headache
- Short attention span
- Difficulty in speaking
- Shaking fingers (tremor)
- Problems with walking or other movement problems
- Frisium having less effect than normal (especially in long term use)
- Dry mouth, constipation
- Loss of appetite, feeling sick (nausea)

Uncommon side effects (may affect up to 1 in 100 people):

- Loss of sexual drive
- Memory difficulties, confusion
- Double vision
- Skin rash
- Weight gain

Not known (frequency cannot be estimated from available data):

- Becoming dependent on Frisium ('physical or mental dependence') (especially in long term use)
- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis)
- Feeling angry

- Changes in the way you walk
- Breathing problems
- Sensitivity to sunlight
- Itchy, lumpy rash (urticaria)
- Muscle spasms or muscle weakness
- Reacting to things more slowly than usual
- Rapid uncontrollable movement of the eyes
- Learning problems
- Abnormally low body temperature

The following side effects are more likely to happen at the start of treatment. They usually last for a short time: feeling tired, dry mouth, constipation, loss of appetite, feeling sick, shaking fingers.

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.

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 sight and reach of children.

Do not use Frisium after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Frisium contains

- Each tablet contains 10mg clobazam as active ingredient.
- They also contain the following ingredients: lactose, maize starch, talc, colloidal silicon dioxide and magnesium stearate.

What Frisium looks like and contents of the pack

The tablets are white and round. Frisium is presented in a blister pack of 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Atnahs Pharma UK Limited

Sovereign House

Miles Gray Road

Basildon, Essex

SS14 3FR

United Kingdom

Manufacturer

Opella Healthcare International SAS

56, Route de Choisy

60200 Compiègne, France

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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