

Frisium® 10mg Tablets

(clobazam)

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.

Your medicine is called Frisium 10mg Tablets, but will be referred to as Frisium throughout this leaflet.

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:

- * You are allergic (hypersensitive) to clozabam, other benzodiazepine medicines or any of the other ingredients of Frisium (see section 6: contents of the pack and other 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 drugs 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 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

- * 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 liver 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.
- * 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.

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

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 diphenenhydramine)
- * 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 the symptoms of acid reflux such as heartburn or acid regurgitation.
- * Ticlopidine - an antiplatelet medication used in patients with an increased risk of stroke
- * Fluconazole - used in the treatment of fungal conditions
- * Dextromethorphan - used to relieve dry, irritating coughs
- * Nebivolol - medicine used to treat high blood pressure.
- * 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 food, drink and 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

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. 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.

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® 10mg Tablets

(clobazam)

Patient Information Leaflet (continued)

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 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 20 mg to 30 mg 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 60 mg each day
- * Your doctor may lower the dose to suit you

Children (6 years and above)

- * The usual dose is 5 mg each day

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' which is 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.

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 and rapid uncontrollable movement of the eyes
- * 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on 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 store above 25°C.
- * Do not take Frisium after the expiry date which is stated on the label. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to
- * If your medicine becomes discoloured or show any other signs of deterioration, ask your pharmacist who will advise you what to do.
- * 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 Contents of the pack and other information

What Frisium contains

Each tablet contains 10mg clobazam.
Other ingredients: lactose, maize starch, talc, colloidal silicon dioxide and magnesium stearate.



What Frisium looks like and contents of the pack

Frisium tablets are round white tablets with company logo on one side and B and a score line and GL on the other side.
Each pack contains 30 tablets.

Manufacturer and Licence Holder

Manufactured by Sanofi Winthorp industrie, 56 route de Choisy au Bac, 60205 Compiègne, France and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

  PL 15184/1522 Frisium 10mg Tablets

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Revision date: 12/03/18

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet
in a format suitable for you

Clobazam Lexon 10mg Tablets

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1 What Clobazam is and what is used for

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Clobazam can be used for:

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- * Mental illness such as schizophrenia (in combination with other treatments)

2 What you need to know before you take Clobazam

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- * You are breast-feeding
- * You have ever had problems with drugs 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 6 years old

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Warnings and precautions

- Talk to your doctor or pharmacist before taking Clobazam
- * 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 Clobazam 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 liver 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.
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 - * Medicines for severe mental illness called ‘antipsychotics’ (such as chlorpromazine, haloperidol, clozapine and pimozide)
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 - * Antihistamines that make you sleepy (such as chlorphenamine, promethazine or diphenenhydramine)
 - * 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 the symptoms of acid reflux such as heartburn or acid regurgitation.
 - * Ticlopidine - an antiplatelet medication used in patients with an increased risk of stroke
 - * Fluconazole - used in the treatment of fungal conditions
 - * Dextromethorphan - used to relieve dry, irritating coughs
 - * Nebivolol - medicine used to treat high blood pressure.
 - * Concomitant use of Clobazam 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 Clobazam. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants to give you.

Clobazam with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

- Do not take Clobazam 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 Clobazam 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. 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.

- 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.

Patient Information Leaflet (continued)

Important information about some of the ingredients of Clobazam
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 Clobazam contains lactose.

3 How to take Clobazam

Always take Clobazam 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. Clobazam 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 Clobazam until your doctor tells you to stop
- * Clobazam 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 20 mg to 30 mg 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 60 mg each day
- * Your doctor may lower the dose to suit you

Children (6 years and above)

- * The usual dose is 5 mg each day

Elderly

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

If you take more Clobazam than you should
If you take more Clobazam 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 Clobazam

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

- * When your doctor says that you can stop taking Clobazam, 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

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

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- * Feeling suicidal
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- * Being aggressive
- * Reacting to things more slowly than usual
- * Eye problems such as double vision and rapid uncontrollable movement of the eyes
- * Difficulty in staying awake or alert
- * Becoming dependent on Clobazam (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.

Reporting of side effects
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6 Contents of the pack and other information

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