

Package leaflet: Information for the user
Clobazam Atnahs 5mg/5ml and 10mg/5ml Oral Suspension
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 Clobazam Oral Suspension is and what it is used for
2. What you need to know before you take Clobazam Oral Suspension
3. How to take Clobazam Oral Suspension
4. Possible side effects
5. How to store Clobazam Oral Suspension
6. Contents of the pack and other information

1. What Clobazam Oral Suspension is and what it is used for

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

Clobazam Oral Suspension can be used to treat:

- 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 Clobazam Oral Suspension

Do not take Clobazam Oral Suspension

- If you are allergic (hypersensitive) to clobazam, other benzodiazepine medicines or any of the other ingredients of this medicine (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

- If 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).
- If you are breast-feeding.
- If you have ever had problems with drugs or alcohol dependence in the past.

- If you suffer from an illness that causes muscle weakness (called 'myastheniagravis').
- If you have liver problems.
- If you have breathing problems.
- You suffer from depression, as this may lead to suicidal thoughts.
- If you stop breathing for short periods during sleep (called 'sleep apnoea syndrome').
- If the patient is 6 months -2 years old, except if the doctor decides this is necessary.

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Clobazam Oral Suspension. Use of Clobazam may lead to a physical addiction. Stopping Clobazam suddenly may lead to side effects. Dependence on Clobazam may occur. Extended use of Clobazam, will lessen the effect it has on your symptoms

Warnings and precautions

Talk to your doctor before taking Clobazam Oral Suspension:

- If you have problems with controlling your movements (called 'spinal or cerebellar ataxia').
- If you have depression, irrational fears and obsessions.
- 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. Alcohol should not be taken during treatment with clobazam as there is an increased risk of experiencing side effects.
- You have a behavioural disorder
- 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.
- You have difficulty digesting medicines. Some patient's 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.

Suicidal thoughts

Some patients have experienced suicidal thoughts while taking medicines containing clobazam, particularly if they are already depressed. 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 Clobazam Oral Suspension if you take it for long periods of time, particularly if you have a history of heavy alcohol or drug use. This means that you may feel that you need to continue treatment with Clobazam Oral Suspension in order to feel well (known as psychological dependence). If you suddenly stop taking Clobazam Oral Suspension 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 Clobazam Oral Suspension 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 Clobazam Oral Suspension is no longer helping to control your symptoms please talk to your doctor, they may suggest you take a short break from this medicine.

Children

Clobazam oral suspension should only be used in children from 6 months to 2 years old, under exceptional situations, where there is a clear epilepsy indication. Drowsiness, difficulties breathing, coma and death may occur if Clobazam oral suspension is taken together with opioids. Clobazam oral suspension 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.

Skin Reactions

There have been very rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Clobazam. 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).

Other medicines and Clobazam Oral Suspension

Please **tell your doctor, pharmacist or nurse** if you are taking, have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because clobazam can affect the way some other medicines work. Also, some medicines can affect the way Clobazam Oral Suspension 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 antidepressants - 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 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 treatment of fungal conditions
- Dextromethorphan – used to relieve dry, irritating coughs
- Nebivolol – medicines used to treat high blood pressure

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 Oral Suspension. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants given to you.

Clobazam Oral Suspension with food, drink and alcohol

Do not drink alcohol while you are taking Clobazam Oral Suspension. This is because there is increased risk of sleepiness and other side effects.

Clobazam may be taken with or without food.

Pregnancy and breast-feeding

Do not take Clobazam Oral Suspension:

- If you are in the first three months of pregnancy
- If you are 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 Oral Suspension 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 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.

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:

1. The medicine has been prescribed for you to treat a medical or dental problem
2. You have taken it according to the instructions given by the prescriber or in the information

provided with the medicine

3. 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.

Important information about some of the ingredients of Clobazam Oral Suspension

Clobazam Oral Suspension contains sorbitol (E420), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217) and Sodium Sorbitol (E420)

This medicine contains 875 mg of Sorbitol in 5 mL, which is equivalent to 175 mg / mL

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217)

These may cause allergic reactions in some people that could occur some time after taking this medicine. The signs may include a rash, swallowing or breathing problems and swelling of your lips, face, throat or tongue. If you have any concerns over whether this medicine is suitable for you, talk to your doctor, pharmacist or nurse.

Sodium

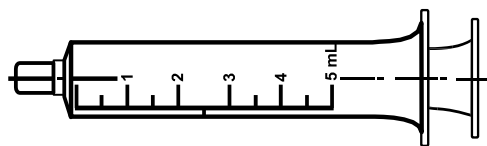
Each ml of Clobazam Oral Suspension contains 3.05 mg of sodium. The sodium content of the maximum daily dose is therefore 183 mg for Clobazam 5mg/5ml Oral Suspension and 91.5 mg for Clobazam 10mg/5ml Oral Suspension. You must take this into account if you are on a controlled sodium diet.

3. How to take Clobazam Oral Suspension

Always take this medicine exactly as your doctor has told you. Clobazam Oral Suspension is usually given for 2 to 4 weeks. After that, your doctor will decide whether you should keep taking this medicine. Check with your doctor or pharmacist if you are not sure.

Method of administration:

The box containing this medicine will contain a 5ml dosing syringe, a dosing adapter and a 30ml dosing cup. Instructions are provided below for using the dosing syringe.

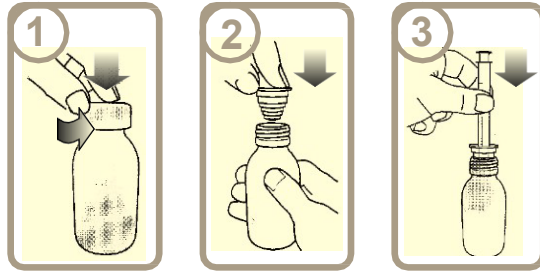


If you have any questions about how to use the syringe, you should ask your pharmacist. This product may settle during storage. **Please shake the bottle well before use.**

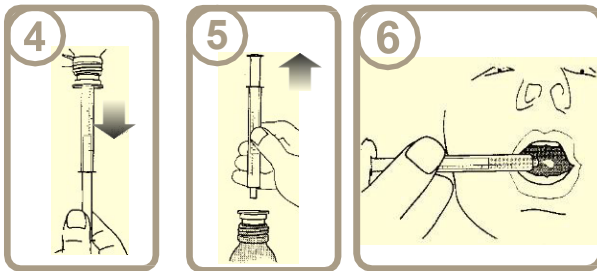
Instructions for use:

- Open the bottle: press the cap and turn it anticlockwise. (*see figure 1*)
- Holding the bottle, take the plastic syringe adapter from the box and insert the adapter firmly into the bottle neck. (*see figure 2*)

- Take the syringe and put it in the adapter opening (*see figure 3*)



- Turn the bottle upside down and fill the syringe with a small amount of suspension by pulling the piston down (*see figure 4*), then push the piston upward in order to remove any possible bubbles. Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor.
- Turn the bottle the right way up. Remove the syringe from the adapter. (*see figure 5*)
- Administer the contents of the syringe into the mouth by pushing the piston to the bottom of the syringe (*see figure 6*) and ensure the medicine is swallowed.



This medicine comes in two strengths. Make sure you follow the dosage instructions for the strength of medicine you have been prescribed.

5mg/5ml: Doses

Adults (Anxiety and Epilepsy)

- The usual dose is 20 mg (20 ml) to 30 mg (30 ml) 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 (60 ml) each day.
- Your doctor may lower the dose to suit you

Use in children (over 2 years) (Epilepsy)

- The usual starting dose is 5mg (5ml) each day or 0.1mg/kg/day in divided doses or as a single dose at night.
- Your doctor will then adjust the dose according to your child's need.

Use in children (6 month-2 years) (Epilepsy)

- The usual starting dose is 0.1mg/kg/day in divided doses twice daily.
- Your doctor will then adjust the dose according to your child's need

Elderly

- The usual dose for anxiety is 10 mg (10 ml) to 20 mg (20 ml) each day.

10mg/5ml: Doses

Adults (Anxiety and Epilepsy)

- The usual dose is 20 mg (10 ml) to 30 mg (15 ml) 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 (30 ml) each day.
- Your doctor may lower the dose to suit you

Use in children (over 2 years) (Epilepsy)

- The usual starting dose is 5mg (2.5ml) or 0.1mg/ kg each day in divided doses or as a single dose at night.
- Your doctor will then adjust the dose according to your child's need.

Use in children (6 month-2 years) (Epilepsy)

- The usual starting dose is 0.1mg/kg/day in divided doses twice daily.
- Your doctor will then adjust the dose according to your child's need.

Elderly

- The usual dose for anxiety is 10mg (5 ml) to 20 mg (10 ml) each day.

After use:

Remove the adapter from the bottle and close the bottle with the plastic screw cap. Wash the adapter and syringe or cup with warm water. Dry and replace them into the box with your medicine.

When you are taking Clobazam Oral Suspension you should not change to any different clobazam containing medicines except under your doctor's supervision.

If you take more Clobazam Oral Suspension than you should

If you take more Clobazam Oral Suspension 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 Clobazam Oral Suspension that is left and the pack. This is so the doctor knows what you have taken.

If you forget to take Clobazam Oral Suspension

- If you have missed a dose take it as soon as you remember.
- 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 dose.

If you stop taking Clobazam Oral Suspension

Keep taking this medicine until your doctor tells you to stop. Do not stop taking Clobazam Oral

Suspension 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 suspension 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, this medicine can cause side effects, although not everybody gets them.

You may feel ill after taking the medicine 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 tipping 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'
- 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 Clobazam 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 Clobazam may lead to a physical addiction. Stopping Clobazam suddenly may lead to side effects. Dependence on Clobazam may occur. Talk to your doctor if you feel you have developed a dependence on Clobazam Oral Suspension.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [national reporting system] . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clobazam Oral Suspension

Keep this medicine out of the sight and reach of children.

Do not use Clobazam Oral Suspension after the expiry date stated on the bottle label and carton after EXP.

The expiry date refers to the last day of that month.

Do not store above 25°C. Use within 28 days of opening.

Keep the bottle in the outer carton in order to protect from light.

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 Clobazam Oral Suspension contains

The active substance (the ingredient that makes the oral solution work) is clobazam.

Each 5ml of Clobazam 5mg/5ml Oral Suspension contains 5mg of clobazam.

Each 5ml of Clobazam 10mg/5ml Oral Suspension contains 10 mg of clobazam.

The other ingredients are sorbitol (E420), xanthan gum (E415), acesulfame potassium (E950), raspberry flavour, sodium propyl parahydroxybenzoate (E217), sodium methyl parahydroxybenzoate (E219), disodium hydrogen phosphate dihydrate, sodium dihydrogen phosphate dihydrate and purified water.

What Clobazam Oral Suspension looks like and contents of the pack

Clobazam Oral Suspension is an off-white viscous suspension with an odour of raspberry supplied in an amber glass bottle.

The contents may settle during storage and should be shaken before use.

Each pack also contains a 5ml oral syringe, syringe adapter and 30 ml measuring cup.

Pack size is 150ml.

Marketing Authorisation Holder

To be completed during nationally

Manufacturer

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Laboratorium Sanitatis, S.L.

Leonardo da Vinci, 11

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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 January 2023.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Tenoretic 100 mg/25 mg film coated tablets**

Reference number *PL 43252/0043*

This is a service provided by the Royal National Institute of Blind People.