

Clobazam Martindale Pharma 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, nurse or pharmacist.
- This medicine has been prescribed for you. 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, pharmacist or nurse. 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 Clobazam which belongs to a group of medicines called benzodiazepines.

Clobazam works by having a calming effect on the brain.

Clobazam Oral Suspension is used to treat:

- Severe anxiety over a short time
- Epilepsy (fits) over a longer time (in combination with other treatments)
- 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 (listed in section 6).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- 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 'myasthenia gravis').
- If you have breathing problems.
- If you stop breathing for short periods during sleep (called 'sleep apnoea syndrome').
- If you have severe liver problems.
- If you are breast-feeding.
- If the patient is 6 months - 2 years old, except if the doctor decides this is necessary.
- You are pregnant or are planning to have a baby (see below under 'Pregnancy, breast-feeding and fertility' for more information).

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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 your liver or kidneys do not work as well as they should.
- If you have ever become dependent upon another drug or alcohol. Alcohol should not be taken during treatment with Clobazam oral suspension 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.
- You are taking any medicinal or non-medicinal products containing cannabidiol, as it may increase the side effects of clobazam.

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.

Other medicines and Clobazam Oral Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription including herbal medicines.

Also, some medicines can affect the way Clobazam works. Especially:

- medicines for epilepsy (such as phenytoin, carbamazepine, stiripentol or valproic acid)
- medicines for depression (such as Monoamine Oxidase Inhibitors (MAOIs), SSRI's 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 'neuroleptics' (such as chlorpromazine, haloperidol and 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 'bipolar disorder' (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.
- nebulivolol - used to treat high blood pressure
- cannabidiol-containing products (medicinal or non-medicinal products).

Concomitant use of Clobazam and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Clobazam together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

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.

Taking 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.

Pregnancy, breast-feeding and fertility

Pregnancy

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 Clobazam 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.

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 Clobazam 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 Clobazam Oral Suspension if you

- are breast-feeding or planning to breast-feed. This is because it may pass into the mother's 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.

Clobazam Oral Suspension contains:

- **Sorbitol (E420):** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
- **Sodium Methyl Hydroxybenzoate (E219) and Sodium Propyl Hydroxybenzoate (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.

3. How to take Clobazam Oral Suspension

Always take this medicine exactly as your doctor or pharmacist 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.

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

5mg/5ml: Doses

Adults (Anxiety and Epilepsy)

The usual dose is 20mg (20ml) to 30mg (30ml) 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 (60ml) 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 (Anxiety)

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

10mg/5ml: Doses

Adults (Anxiety and Epilepsy)

The usual dose is 20mg (10ml) to 30mg (15ml) 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 (30ml) 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.

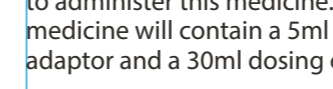
Elderly (Anxiety)

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

Method of administration

This product may settle during storage. **Please shake well before use.**

Your doctor, pharmacist or nurse will show you how to administer this medicine. The box containing this medicine will contain a 5ml dosing syringe, a dosing adaptor and a 30ml dosing cup.

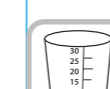


1ml syringe is provided only with the 150ml pack size of Clobazam 5mg/5ml Oral Suspension and is for patients who require small doses of less than 1ml.

1ml syringe each numbered increment is 0.1ml equivalent to 0.1mg Clobazam 5mg/5ml Oral Suspension. The intermediate increments are 0.05ml equivalent to 0.05mg Clobazam 5mg/5ml Oral Suspension. The smaller increments are 0.01ml equivalent to 0.01mg Clobazam 5mg/5ml Oral Suspension.



5ml syringe each numbered increment is 1ml equivalent to 1mg of Clobazam 5mg/5ml Oral Suspension and 2mg of Clobazam 10mg/5ml Oral Suspension. The smaller increments are 0.2ml or 0.2mg of Clobazam 5mg/5ml Oral Suspension and 0.4mg of Clobazam 10mg/5ml Oral Suspension.



30ml dosing cup. Each numbered increment is 5ml - equivalent to 5mg of Clobazam 5mg/5ml Oral Suspension and 10mg of Clobazam 10mg/5ml Oral Suspension.

Instructions are provided overleaf for using the dosing syringe. If you have any questions about the dose you should use or how to use the syringe, you should ask your pharmacist.

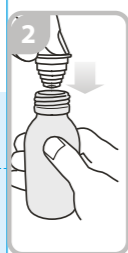
Instructions for use:

Open the bottle: press the cap and turn it anticlockwise (figure 1)

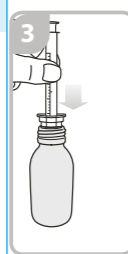


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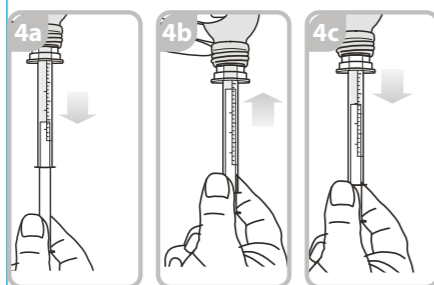
Holding the bottle, take the plastic syringe adaptor from the box and insert the adaptor into the bottle neck (figure 2). Ensure it is well fixed.



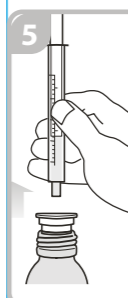
Take the syringe and put it in the adaptor opening (figure 3). Turn the bottle upside down.



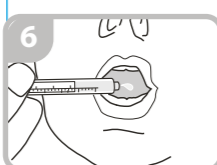
Fill the syringe with a small amount of suspension by pulling the piston down (figure 4a), then push the piston upward in order to remove any possible bubble (figure 4b). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 4c).



Turn the bottle the right way up. Remove the syringe from the adaptor (figure 5)



Administer the contents of the syringe into the mouth by pushing the piston to the bottom of the syringe (figure 6) and ensure the medicine is swallowed.



Remove the adaptor from the bottle and close the bottle with the plastic screw cap.

Wash the adaptor and the syringe with warm water. Dry them with a clean paper towel and replace them into the box with your medicine.

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 **immediately**. Do not drive yourself because you may start to feel sleepy.

If you forget to take Clobazam Oral Suspension If you have missed a dose take it as soon as you remember unless it is almost time for the next one then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Clobazam Oral Suspension Do not stop taking your medicine without telling your doctor as he may gradually reduce your dose before stopping it completely. If stopped suddenly, you may have unpleasant side effects including stress (anxiety), confusion, or depression. You may also lose your appetite and have difficulty sleeping (see Section 2 'Dependence, tolerance and withdrawal').

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

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious Side Effects:

Tell your doctor immediately 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 Clobazam oral suspension (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 the 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'.

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.
- Clobazam oral suspension 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 when used for long time or with high doses and is reversible.
- Memory difficulties, confusion.
- Double vision.
- Skin rash.
- Weight gain.

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

- Becoming dependent on Clobazam oral suspension ('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 or 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 Website: <http://www.mhra.gov.uk/yellowcard> 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 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.

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 10mg of clobazam.

• The other ingredients are sorbitol (E420), xanthan gum (E415), acesulfame potassium (E950), raspberry flavour, sodium propyl hydroxybenzoate (E217), sodium methyl hydroxybenzoate (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.

Pack sizes are 100ml, 150ml and 250ml.

Marketing Authorisation Holder

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If you would like any more information, or would like the leaflet in a different format, please contact medical information at the above address.

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