

PACKAGE LEAFLET

Package leaflet: Information for the user

Clobazam Northumbria 5 mg/5ml Oral Suspension

Clobazam Northumbria 10 mg/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.

The name of your medicine is Clobazam Northumbria 5 mg/5ml or 10 mg/5ml Oral Suspension but will be referred to as Clobazam Northumbria or 'this medicine' throughout this leaflet.

What is in this leaflet

1. What Clobazam Northumbria is and what it is used for
2. What you need to know before you take Clobazam Northumbria
3. How to take Clobazam Northumbria
4. Possible side effects
5. How to store Clobazam Northumbria
6. Contents of the pack and other information

1. What Clobazam Northumbria is and what it is used for

Clobazam belongs to a group of medicines called 'benzodiazepines'. It works by having a calming effect on the brain.

Clobazam Northumbria can be used for:

- severe anxiety over a short time
- epilepsy (fits) in adults and children aged 6 years and over (together with other anticonvulsant treatments)
- mental illness such as schizophrenia (in combination with other treatments).

2. What you need to know before you take Clobazam Northumbria

Do not take Clobazam Northumbria if:

- you are allergic (hypersensitive) to clobazam, other benzodiazepine medicines or any of the other ingredients of this medicine (see section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you are pregnant or are planning to have a baby (see section 2 'Pregnancy, breast-feeding and fertility')
- 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 ('myasthenia gravis')
- you have breathing problems
- you stop breathing for short periods while you sleep ('sleep apnoea syndrome')
- you have severe liver problems
- 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 this medicine.

Warnings and precautions

Note: Make sure that you receive the same clobazam medicine every time you collect your prescription unless your doctor has agreed to change to a different clobazam medicine. If the appearance of this medicine is not the same as usual or if the dosage instructions have changed, speak to your doctor or pharmacist as soon as possible to make sure you have the right medicine.

Talk to your doctor or pharmacist before taking Clobazam Northumbria if:

- you have problems with controlling your movements ('spinal or cerebellar ataxia')
- you have depression, irrational fears or 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 increased sensitivity to adverse reactions in the elderly such as drowsiness, dizziness and muscle weakness. There is also an increased risk of fall that might 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 Clobazam is taken together with opioids. Clobazam 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 any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

Suicidal thoughts

Tell your doctor straight away if you start thinking about suicide or harming yourself. Some patients have had suicidal thoughts while taking medicines containing clobazam, especially if they were also depressed.

Dependence, withdrawal and tolerance

You may become dependent on clobazam if you take it for a long period of time, especially if you regularly drink a lot of alcohol or use drugs. This means that you may feel that you need to continue the treatment with clobazam in order to feel well ('psychological dependence').

If you suddenly stop taking Clobazam Northumbria you may get:

- worsening of the symptoms you were originally being treated for
- mood changes, feeling anxious, restless, depressed or confused
- sleep problems
- loss of appetite.

These are known as 'withdrawal symptoms' and can be avoided by slowly reducing your dose. Talk to your doctor or pharmacist if you are worried about 'psychological dependence' or 'withdrawal symptoms'.

If you take Clobazam Northumbria for epilepsy for a long period of time then it is possible that you may become 'tolerant' to it. This means that it will not work as well as it did when you first started taking it. Talk to your doctor if you feel that Clobazam Northumbria is no longer helping to control your symptoms - they may suggest that you take a short break from this medicine.

Other medicines and clobazam

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 clobazam can affect the way some other medicines work. Also, some other medicines can affect the way clobazam works.

In particular, tell your doctor or pharmacist 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 serious mental illness called 'antipsychotics' (such as chlorpromazine, haloperidol, clozapine and pimazide)
- 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 feel sleepy (such as chlorphenamine, promethazine or diphenhydramine)
- lithium, used for a serious mental health problem called 'bipolar disorder' (mood changes between a state of high excitability or exaggerated emotions and depression)
- cimetidine, used to treat stomach ulcers and heartburn
- omeprazole, used to treat symptoms conditions
- 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, medicines used to treat high blood pressure.
- cannabidiol-containing products (medicinal or non-medicinal products).

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

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

When taking this medicine you should not start taking any different medicines containing clobazam unless your doctor tells you to. If you do, it may cause breathing difficulties and sleepiness.

Anaesthetics

If you are going to have an anaesthetic, tell your doctor or anaesthetist that you are taking Clobazam Northumbria. This is because they may need to change the amount of medicine (anaesthetic or muscle relaxant) they give to you.

Clobazam Northumbria with alcohol

Do not drink alcohol while taking this medicine. This is because there is an 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 clobazam 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 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 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 feel 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

- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine
- 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 Northumbria contains:

Liquid Maltitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

E219 Sodium methyl parahydroxybenzoate and E217 Sodium propyl parahydroxybenzoate.

May cause allergic reactions (possibly delayed).

Sodium

This medicine contains 2.9 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0.1% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Clobazam Northumbria

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If low doses are required, the 5mg/5ml strength product is the most suitable presentation. If high doses are required, the 10mg/5ml strength product is the most suitable presentation.

Taking this medicine

- Clobazam Northumbria 10 mg/5ml Oral Suspension contains 10 milligram (mg) of clobazam in each 5 millilitre (ml) of suspension, equivalent to 2mg per ml.
- Clobazam Northumbria 5 mg/5ml Oral Suspension contains 5 milligram (mg) of clobazam in each 5 millilitre (ml) of suspension, equivalent to 1mg per ml.
- Take this medicine by mouth.
- This product must not be mixed with other medicinal products or beverages.
- Always use the dosing pipette (oral syringe) supplied with the pack.
- This medicine can be taken with or without food. It is recommended that the dose be followed with a glass (approximately 200ml) of water.

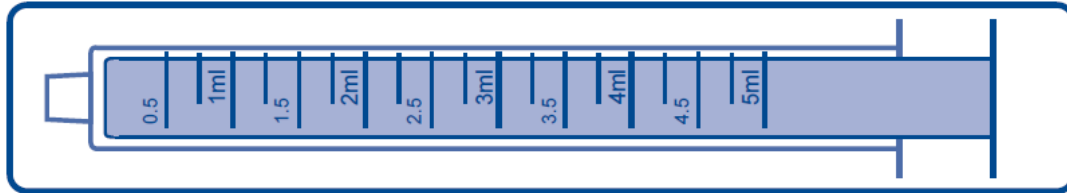
How much to take

	5mg/5mL	10mg/5mL
Adults	The usual dose is 20-30mL (20-30mg) each day. This can be taken as 2 separate doses or as a single dose at night. Your doctor may increase your dose to up to 60mL (60 mg) each day. Your doctor may lower the dose to suit you.	The usual dose is 10-15mL (20-30mg) each day. This can be taken as 2 separate doses or as a single dose at night. Your doctor may increase your dose to up to 30mL (60 mg) each day. Your doctor may lower the dose to suit you.
Elderly	The usual dose for anxiety is 10-20mL (10-20mg) each day.	The usual dose for anxiety is 5-10mL (10-20mg) each day

Children (6 years and over)	The usual starting dose is 5 mg each day. Your doctor will then adjust the dose according to your child's need.
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Method of administration:

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



5 ml pipette, sections are numbered at 0.5ml intervals and the smaller increments are 0.2 ml.

Clobazam Northumbria 10 mg/5ml Oral Suspension: 1 ml is equivalent to 2 mg clobazam.

Clobazam Northumbria 5 mg/5ml Oral Suspension: 1 ml is equivalent to 1 mg clobazam.

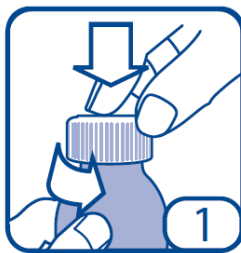
If you are taking a large dose, you may have to measure the dose with the pipette more than one time. It may be helpful to write on a piece of paper the amount of times you have to use the pipette. Each time you take the dose, tick off a dose on the paper. Alternatively, ask your pharmacist for a measuring cup, which can be used instead of the pipette.

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

Turn the bottle upside down two or three times before using it. This helps the medicine come out of the bottle easier.

Instructions for use:

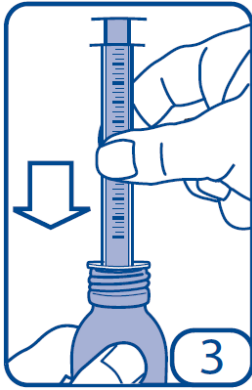
- Open the bottle: press the cap and turn it anticlockwise (figure 1).



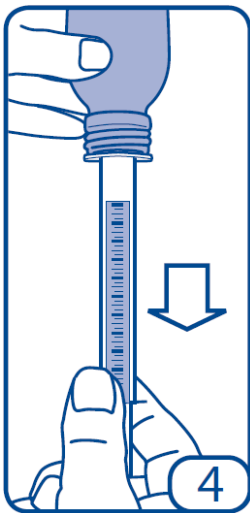
- On using the bottle for the first time, the bottle adaptor must be fitted. It will then stay in place for future doses. Holding the bottle, take the plastic adaptor from the box and insert the adaptor into the bottle neck (figure 2). Ensure it is well fixed.



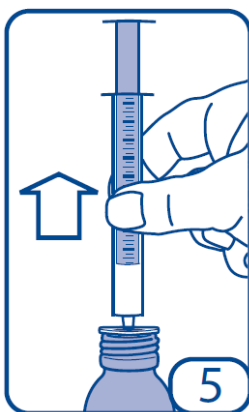
- Take the pipette and put it in the adaptor opening (figure 3).



- Hold the pipette in place and turn the bottle upside down. Fill the pipette with a small amount of the suspension by pulling the piston down (figure 4), then push the piston up in order to remove any possible air.
- Still holding the pipette in place, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4).



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



- Administer the contents of the pipette into the mouth by pushing the piston to the bottom of the pipette and ensure the medicine is swallowed.

Do not remove the adaptor from the bottle neck, it is intended to stay in place. Close the bottle with the plastic screw cap.

Wash the pipette with warm water. Dry it with a clean paper towel and replace into the box with your medicine.

Duration of treatment

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

If you take more Clobazam Northumbria than you should

If you, or anyone else, takes too much of this medicine you should go to your nearest hospital emergency department or tell your doctor immediately. Remember to take the medicine and pack with you. This is so the doctor knows what you have taken. Do not drive yourself because you may start to feel sleepy.

If you forget to take Clobazam Northumbria

If you miss a dose do not worry. Just carry on taking your normal dose when the next one is due. Do not take a double dose to make up for the one you missed.

If you stop taking Clobazam Northumbria

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 you can stop taking clobazam, you need to do this gradually. Your doctor will help you to do this.
- Stopping this medicine suddenly 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you feel ill after taking Clobazam, or notice unusual or unexpected symptoms, tell your doctor.

Stop taking Clobazam Northumbria and see a doctor or go to a hospital straight away if you notice the following serious side effect - you may need urgent medical treatment:

- allergic reaction - the signs may include swelling of your face, lips, tongue or throat, difficulty breathing or swallowing, severe itching of your skin with raised lumps.

Stop taking this medicine and see a doctor or go to a hospital straight away if you notice the symptoms listed above.

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 clobazam (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 gets 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 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 clobazam ('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 or your child gets 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 Website: 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 Clobazam Northumbria

Keep this medicine out of the sight and reach of children. Keep the bottle in the outer carton in order to protect from light.

Do not store above 25°C. Do not freeze.

Do not use 28 days after you first open it. Take it back to the pharmacy.

Do not use this medicine after the expiry date (month, year) which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not use Clobazam Northumbria if you notice anything wrong with the medicine. Talk to your doctor or pharmacist.

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

6. Contents of the pack and other information

What Clobazam Northumbria contains

- The active substance is clobazam.
- Each 5 ml of Clobazam Northumbria 10 mg/5ml Oral Suspension contains 10 mg of clobazam, equivalent to 2mg per ml.
- Each 5 ml of Clobazam Northumbria 5 mg/5ml Oral Suspension contains 5 mg of clobazam, equivalent to 1mg per ml.
- The other ingredients are purified water, liquid maltitol (E965), disodium phosphate dihydrate (E339), citric acid monohydrate (E330), xanthan gum (E415), sodium methyl parahydroxybenzoate (E219), Raspberry flavour, acesulfame potassium (E950), sodium propyl parahydroxybenzoate (E217).

What Clobazam Northumbria looks like and contents of the pack

Clobazam Northumbria is an off-white suspension with an odour of raspberry supplied in 150ml amber glass bottles. Each pack contains one bottle of suspension, a 5 ml dosing pipette and a bottle adaptor.

Marketing Authorisation Holder and Manufacturer:**Marketing Authorisation Holder:**

Northumbria Pharma Limited.,
NETPark,
Thomas Wright Way,
Sedgefield,
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TS21 3FD,
United Kingdom

Manufacturer:

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1 Thane Road West,
Nottingham NG2 3AA,
United Kingdom

Is this leaflet hard to see or read? Please contact medical information at the above address.

This leaflet was last revised in June 2023