

Clobazam Accord 10mg Tablets

Read 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 later.
- 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.

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1 What Clobazam 10mg Tablets are and what they are used for

Clobazam 10mg Tablets contain a medicine called clobazam. This belongs to a group of medicines called benzodiazepines. It works by having a calming effect on the brain.

Clobazam 10mg Tablets 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 Clobazam 10mg Tablets

Do not take Clobazam 10mg Tablets:

- if you are allergic to clobazam or any other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue
- if you have a very severe form of muscle weakness called myasthenia gravis
- if you stop breathing for short periods during sleep (called 'sleep apnoea syndrome')
- if you have liver problems
- 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 the patient is under 6 years old
- if you have breathing problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clobazam 10mg Tablets

- 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. Do not drink alcohol during treatment with Clobazam 10mg Tablets as there is an increased risk of experiencing side effects
- 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 falling that may result in serious injury
- if you have difficulty digesting medicines. Patients with liver problems may not metabolise (break down) medicines adequately which means the medicine may remain in the body for longer than normal. This may result in side effects. If you are known to poorly metabolise certain medicines, please speak to your doctor.

Children

Do not give Clobazam 10mg Tablets to children under 6 years of age (see section 'Do not take Clobazam 10mg Tablets:').

Other medicines and Clobazam 10mg Tablets

Please 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 10mg Tablets can affect the way some other medicines work. Also some medicines can affect the way Clobazam 10mg Tablets work.

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), tricyclic anti-depressants such as trazodone or Selective Serotonin Re-uptake Inhibitors (SSRIs) such as fluvoxamine or paroxetine)
- medicines for severe mental illness called 'antipsychotics' (such as chlorpromazine, haloperidol, clozapine and pimozide)
- painkillers (such as medicines containing codeine, dihydrocodeine or morphine)
- sleeping tablets (such as zolpidem)
- tranquilisers (such as diazepam, temazepam or lorazepam)
- muscle relaxants (such as baclofen)
- antihistamines that make you sleepy (such as chlorphenamine, promethazine or diphenhydramine)
- lithium - used for a mental illness called 'manic-depressive illness' (mood changes between a state of high excitability or exaggerated emotions and depression)
- cimetidine - used to treat ulcers and heartburn
- omeprazole - used to treat 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
- opioids - concomitant use of Clobazam 10mg Tablets 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 10mg Tablets 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 10mg Tablets. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants to give you.

Clobazam 10mg Tablets with food, drink and alcohol

- do not drink alcohol while taking Clobazam 10mg Tablets. This is because there is an increased risk of sleepiness and other side effects.

Pregnancy, breast-feeding and fertility

Do not take Clobazam 10mg Tablets if you are:

- a woman of childbearing potential and are not using contraception
- 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 10mg Tablets are 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

If you feel sleepy after taking this medicine, do not drive or use dangerous machinery. If you have been on clobazam for epilepsy, it is wise not to drive during withdrawal of medication and the following six months.

Do not drink alcohol.

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 10mg Tablets contain Lactose

If you have been told by your doctor that you have an intolerance to lactose, contact your doctor before taking this product.

3 How to take Clobazam 10mg Tablets

Always take this medicine exactly as your doctor has told you. 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 given with or without food.

Adults

The recommended starting dose for the treatment of anxiety or epilepsy is 20mg to 30mg daily in divided doses but sometimes as a single dose at night.

Your doctor may increase the dose (up to a maximum of 60mg daily) or decrease the dose to suit you.

Children aged six years and over

The recommended starting dose is 5mg daily and a recommended maintenance dose of 0.3mg to 1mg/kg body weight daily. There has not been enough use of Clobazam in children under six years to be able to suggest a suitable dose. The tablets should be swallowed whole with water; do not chew them.

Elderly

The recommended dose for anxiety is 10mg to 20mg each day.

People with kidney or liver problems

It is recommended that lower doses (10mg to 20mg daily) are used.

If you forget to take Clobazam 10mg Tablets

If you forget 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 tablet.

If you take more Clobazam 10mg Tablets than you should

If you take more Clobazam 10mg Tablets 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 stop taking Clobazam 10mg Tablets

Keep taking this medicine until your doctor tells you to stop. Do not stop taking Clobazam 10mg Tablets just because you feel better.

- When your doctor says that you can stop taking Clobazam 10mg Tablets, you need to do this gradually. Your doctor will help you to do this.
- Stopping the tablets can make you feel stressed (anxious), 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, Clobazam 10mg Tablets can cause side effects, although not everybody gets them. You may feel ill after taking the tablets, or notice unusual or unexpected symptoms. If this happens, tell your doctor.

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

Common (may affect up to 1 in 10 people)

- feeling irritable or restless.

Uncommon (may affect up to 1 in 100 people)

- poor memory (amnesia) while taking Clobazam 10mg Tablets or showing unusual behaviour
- nightmares
- feeling anxious
- believing things which are not true (delusions)
- increased possibility of tripping or falling, especially in elderly patients.

Not known (frequency cannot be estimated from available data)

- sleeping problems that get worse after taking this medicine
- sensing things which are not there (hallucinations)
- being less aware of your environment, especially in the elderly
- feeling suicidal
- blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson Syndrome'
- a severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This is something called 'Toxic epidermal necrolysis'.

If you get any of the above side effects, your doctor may decide that your treatment needs to be stopped. These side-effects are more likely to happen in elderly people and children.

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days, or if you notice any side effects not listed in this leaflet.

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

- difficulty in staying awake or alert.

Common (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 walking or other movement problems
- Clobazam 10mg Tablets having less effect than normal (especially in long term use)
- dry mouth, constipation
- loss of appetite, feeling sick (nausea).

Uncommon (may affect up to 1 in 100 people)

- loss of sex drive
- memory difficulties, confusion
- double vision
- skin rash
- weight gain.

Not known (frequency cannot be estimated from available data)

- becoming dependent on Clobazam 10mg Tablets ('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
- itching, 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.

If you take this medicine for a long time, you are more likely to get the following side effects: anxiety, confusion, depression, loss of appetite and difficulty sleeping.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Clobazam 10mg Tablets

Keep the pack in a safe place. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date (month and year) printed after "EXP" on the box. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help protect the environment.

6 Contents of the pack and other information

What Clobazam 10mg Tablets contain

The active substance is clobazam. Each tablet contains 10mg of clobazam. The other ingredients are Lactose monohydrate, Cellulose microcrystalline, Sodium starch glycolate, Talc, Magnesium stearate.

What Clobazam 10mg Tablets look like and contents of the pack

Clobazam 10mg Tablets are whitish and round marked with a score line on one side and 'CB 10' on the other.

Each pack of Clobazam 10mg Tablets contains 30 tablets.

Marketing Authorisation holder

Accord Healthcare Limited
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Manufacturer

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If you would like a leaflet with larger text, please contact 01271 385257