

SCHEDULING STATUS

S5

CLOBAZAM 10 ADCO, 10 mg (tablets)

CLOBAZAM 20 ADCO, 20 mg (tablets)

Clobazam

CLOBAZAM 10 ADCO contains sugar, 92 mg lactose monohydrate

CLOBAZAM 20 ADCO contains sugar, 184 mg lactose monohydrate

Read all of this leaflet carefully before you start taking CLOBAZAM ADCO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- CLOBAZAM ADCO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What CLOBAZAM ADCO is and what it is used for

CLOBAZAM ADCO contains the active substance clobazam.

CLOBAZAM ADCO is used to treat anxiety in neurotic patients and for pre-operative medication.

CLOBAZAM ADCO can also be effective in relieving acute symptoms of alcohol withdrawal syndrome.

2. What you need to know before you take CLOBAZAM ADCO

Do not take CLOBAZAM ADCO:

- if you are hypersensitive (allergic) to clobazam or any of the other ingredients of CLOBAZAM ADCO (listed in section 6)
- if you have a history of drug or alcohol dependence
- 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 in your first trimester of pregnancy or breastfeeding your baby
- if the patient is under 3 years.

Warnings and precautions

Take special care with CLOBAZAM ADCO:

- if you experience any memory loss, please inform your doctor.
- if you have existing muscle weakness or experience any muscle weakness while being treated.
- if you have existing depression or aggression problems.
- if you have ever become dependent upon another drug or alcohol. Alcohol should not be taken during treatment with CLOBAZAM ADCO as there is an increased risk of experiencing side effects.
- if you experience any skin reaction during treatment with CLOBAZAM ADCO.
- if you have chronic or acute breathing problems.
- if you have kidney or liver problems.
- if you are over 65 or debilitated. 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.
- if you are a poor CYP2C19 metaboliser.
- if you are drinking alcohol during treatment.
- if you are using any opioids (pain medication) or any other benzodiazepines.
- if you are using any barbiturates (to treat anxiety or sleep disorders), antihistamines (to treat allergies), narcotics (to induce sleep) or other central nervous depressants (to treat anxiety, panic attacks, seizures, insomnia (trouble to sleep), etc.).

The medicines prescribed to reduce seizures have been associated with a rare but serious reaction called Drug Reaction with Eosinophilia and Systemic Symptoms, or DRESS.

This serious sensitivity is a reaction of the immune system that can cause severe swelling (inflammation) throughout the body, or injury to organs, including the liver, kidneys, lungs, heart, or pancreas. It can lead to hospitalisation and damage or failure of these organs and may progress to death, especially if treatment is delayed.

Do not stop taking CLOBAZAM ADCO without first talking to your healthcare professional. Stopping CLOBAZAM ADCO suddenly can cause uncontrolled seizures.

Call your healthcare professional and seek immediate medical attention if you develop any of the following symptoms at any time while taking CLOBAZAM ADCO:

- Fever
- Swollen lymph nodes
- Sore throat
- Skin rash (may or may not be present)
- Swelling of your face or eyes
- Painful sores in the mouth or around the eyes
- Trouble swallowing or breathing
- Yellowing of your skin or eyes
- Unusual bruising or bleeding
- Severe fatigue and weakness
- Shortness of breath or exercise intolerance

PATIENT INFORMATION LEAFLET

- Severe muscle pain

Other medicines and CLOBAZAM ADCO

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Antipsychotics (such as chlorpromazine, haloperidol, clozapine and pimozide).
- Hypnotics, anxiolytics/sedative (medicines that work on the central nervous system to relieve anxiety, aid sleep, or have a calming effect).
- Antidepressant agents (such as Monoamine Oxidase Inhibitors (MAOIs) or tricyclic antidepressants such as trazodone, or Selective Serotonin Re-uptake Inhibitors (SSRIs) such as fluvoxamine or paroxetine).
- Narcotic analgesics and opioids (medicines containing codeine, dihydrocodeine, morphine, fentanyl, oxycodone and, methadone).
- Anti-convulsant medicines (such as phenytoin, carbamazepine, stiripentol or valproic acid).
- Anaesthetics (medicine that is administered during an operation).
- Sedative antihistamines (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)).
- Muscle relaxants (such as baclofen) and nitrous oxide (laughing gas).
- CYP2C19 inhibitors (such as fluconazole (used to treat fungal conditions), fluvoxamine (SSRI, used to treat depression) and ticlopidine (an antiplatelet medication used in patients with an increased risk of stroke).
- CYP2D6 substrates such as Dextromethorphan (used to relieve dry, irritating coughs), pimozide (used to treat severe mental illness), paroxetine (SSRI, used to treat depression), nebivolol (used to treat high blood pressure).

CLOBAZAM ADCO with food and drink

Be careful how much alcohol you drink. Due to the combined effect of CLOBAZAM ADCO and alcohol it can increase the effects of CLOBAZAM ADCO e.g., sedation.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CLOBAZAM ADCO.

CLOBAZAM ADCO is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception.

Since CLOBAZAM ADCO is found in the breastmilk, CLOBAZAM ADCO should not be given to breastfeeding mothers.

Fertility

No human data available.

Driving and using machines

CLOBAZAM ADCO may cause sedation, memory loss, impaired concentration and impaired muscular function which may adversely affect your ability to drive or use machines.

It is not always possible to predict to what extent CLOBAZAM ADCO may interfere with your daily activities. You should ensure that you do not engage in the driving of a vehicle or use of machines until you are aware of the measure to which CLOBAZAM ADCO affects you.

CLOBAZAM ADCO contains lactose monohydrate

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

3. How to take CLOBAZAM ADCO

Do not share medicines prescribed for you with any other person.

Always take CLOBAZAM ADCO exactly as your doctor has instructed you with an adequate amount of liquid. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide on your starting dose.

The normal adult dose ranges between 10 – 30 mg daily. Doses of 20 mg and above should preferably be given at bedtime or as divided doses.

Treatment will usually start with the lowest recommended dose and the maximum dose should not be exceeded.

Use in children

The daily dose should be halved for children.

Elderly people

For elderly, debilitated and light-weight patients, the daily dose should be halved.

The overall duration of treatment should not be more than 8 – 12 weeks, including a tapering off process.

If your doctor extends treatment beyond this period, it should not take place without re-evaluation of your status.

Your doctor will tell you how long your treatment with CLOBAZAM ADCO will last. Do not stop treatment early because you may experience headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. If you have the impression that the effect of CLOBAZAM ADCO is too strong or too weak, tell your doctor or pharmacist.

If you take more CLOBAZAM ADCO than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of CLOBAZAM ADCO

Do not take a double dose to make up for forgotten individual doses.

If you stop taking CLOBAZAM ADCO

If you suddenly stop taking CLOBAZAM ADCO you may experience headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.

Your doctor may suggest you reduce the dose gradually before stopping treatment.

4. Possible side effects

CLOBAZAM ADCO can have side effects.

Not all side effects reported for CLOBAZAM ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLOBAZAM ADCO, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking CLOBAZAM ADCO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOBAZAM ADCO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- respiratory depression (a breathing disorder characterized by slow and ineffective breathing),
- respiratory failure particularly in patients with pre-existing compromised respiratory function e.g., in patients with bronchial asthma or brain damage,
- photosensitivity reaction (an immune system reaction that is triggered by sunlight causing itchy patches or redness),
- urticaria (also known as hives, is an outbreak of swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly),
- Stevens-Johnson syndrome (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters),
- toxic epidermal necrolysis (symptoms include a painful, red area that spreads quickly, the skin may peel without blistering and fever),
- hypothermia (when your body loses heat faster than it can produce heat).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- decreased appetite,
- irritability,
- aggression,

PATIENT INFORMATION LEAFLET

- restlessness,
- Depression (pre-existing depression may be unmasked)
- medicine tolerance (when your body adapts to the continued presence of the medicine and doesn't respond to the medicine as well anymore),
- agitation (a state of anxiety or nervous excitement),
- somnolence (a strong desire to sleep and a feeling of drowsiness),
- sedation,
- dizziness,
- disturbance in attention,
- slow speech/dysarthria (slurred speech)/speech disorder,
- headache,
- tremor,
- ataxia (impaired balance or coordination),
- dry mouth,
- nausea,
- constipation,
- fatigue, especially at the beginning of treatment.

Less frequent side effects

- abnormal behaviour,
- confessional state (confused thinking and reduced awareness of surroundings),
- anxiety (intense and persistent worry and fear about everyday),
- delusion (believing things that isn't true),
- nightmare,
- loss of libido (sexual drive),
- emotional poverty,
- amnesia (memory loss that may be associated with abnormal behaviour),
- memory impairment (changes in your memory),
- anterograde amnesia (loss of the ability to recall the recent past but long-term memories are still intact),
- depression of mood and affect
- lethargy
- increased motor activity
- decreased motor activity
- paradoxical reactions (inconsistent or contradictory) such as an excess
- excitability with rage
- diplopia (double vision),
- rash
- weight increase,
- increased possibility of tripping or falling, especially in elderly patients.
- fall

PATIENT INFORMATION LEAFLET

Unknown frequency

- dependence (becoming dependent of CLOBAZAM ADCO),
- initial insomnia (problem falling asleep and staying asleep),
- anger,
- hallucination (seeing things that isn't real),
- psychotic disorder (a mental disorder characterised by a disconnection from reality),
- poor sleep quality,
- suicidal ideation (to think or plan suicide),
- cognitive disorder (disorders that affect cognitive abilities including learning, memory, perception and problem solving),
- altered state of consciousness (particularly in elderly patients, may be combined with respiratory disorders),
- nystagmus (involuntary movement of the eye causing the eye to rapidly move from side to side),
- gait disturbance (change in the way you walk),
- muscle spasms,
- muscle weakness,
- slow response to stimuli (slow reaction time).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CLOBAZAM ADCO.

5. How to store CLOBAZAM ADCO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original container

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What CLOBAZAM ADCO contains

The active substance(s) is 10 mg clobazam in CLOBAZAM 10 ADCO and 20 mg clobazam in CLOBAZAM 20 ADCO.

The other ingredient(s) are:

PATIENT INFORMATION LEAFLET

colloidal silicon dioxide, corn starch, hydroxy propyl cellulose, lactose monohydrate, magnesium stearate, talc.

What CLOBAZAM ADCO looks like and contents of the pack

CLOBAZAM 10 ADCO tablets are presented as white to off white, oval shaped, uncoated tablets with functional score on one side and “C” and “M” debossed on the other side.

CLOBAZAM 20 ADCO tablets are presented as white to off white, oval shaped, uncoated tablets with functional score on one side and “C” and “L” debossed on the other side.

100's count bottle pack for CLOBAZAM 10/20 ADCO

40 ml HDPE container, utilizing 33 mm child resistant (CR) closure with induction sealing wad. Puritan cotton coil 9 grm/yard.

1000's count bottle pack for CLOBAZAM 10 ADCO

250 ml HDPE containers, utilizing 53 mm continuous thread (CT) Screw cap closure with induction sealing wad. Puritan cotton coil 9 grm/yard.

1000's count bottle pack for CLOBAZAM 20 ADCO

400 ml HDPE containers, utilizing 53 mm continuous thread (CT) Screw cap closure with induction sealing wad. Puritan cotton coil 9 grm/yard.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand 1685

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

25 January 2025

Registration/Application number

CLOBAZAM 10 ADCO: 55/2.6/0546

CLOBAZAM 20 ADCO: 55/2.6/0547