

CLOCENT 10 Tablets BP

Clobazam 10mg

What is in this leaflet

1. What CLOCENT 10 is used for
2. How CLOCENT 10 works
3. Before you use CLOCENT 10
4. How to use CLOCENT 10
5. While you are using it
6. Side effects
7. Storage and Disposal of CLOCENT 10
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What CLOCENT 10 is used for

CLOCENT 10 can be used for:

- Prolonged or sudden severe anxiety.
- Epilepsy (fits) not adequately stabilized as adjunctive therapy.
- Depression or anxiety associated with depression.
- Mental illness such as schizophrenia or other psychotic illness (in combination with other medication)

How CLOCENT 10 works

CLOCENT 10 contains the active ingredient Clobazam. This belongs to a group of medicines called benzodiazepines. It works by having a calming effect on the brain

Before you use CLOCENT 10

- When you must not use it

- You are allergic (hypersensitive) to clobazam, other benzodiazepine medicine or any of the other ingredients of CLOCENT 10 (listed in ingredients below).
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have ever had problems with medicines, drugs, or alcohol dependence in the past.
- You suffer from an illness that causes muscle weakness (called 'myasthenia gravis').
- If you are in first three months of pregnancy or breast-feeding.
- You have severe liver problems
- You have severe breathing problems.
- You Stop breathing for short periods during sleep (called 'sleep apnoea syndrome')
- Your child is under 6 years of age.
- You have problems of sugar intolerance or absorption.

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking CLOCENT 10

- Before you start to use it

Check with your doctor or pharmacist before taking your medicine if:

- You have problems with controlling your movements (called 'spinal or cerebellar ataxia')
- You have kidney problems.
- You have liver problems.
- If you have depression, anxiety.
- Before taking any dietary supplements and recreational products containing cannabidiol, as it may increase the side effects of clobazam.
- If you are consuming any medicinal products containing cannabidiol, as it may increase the side effects of clobazam

Suicidal thoughts: Some individuals (particularly in children and adolescent) have experienced suicidal thoughts while taking medicines containing clobazam. 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 CLOCENT 10 if you take it for long periods of time or in high dose, particularly if you have a history of heavy alcohol or medicinal use. This means that you may feel that you need to continue treatment in order to feel well (known as psychological dependence).

If you suddenly stop taking CLOCENT 10 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 CLOCENT 10 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 CLOCENT 10 is no longer helping to control your symptoms, please talk to your doctor.

If you are not sure if any of the above

apply to you, talk to your doctor or pharmacist before taking CLOCENT 10

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

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 fluvoxamine or paroxetine).
- Medicines for severe mental illness called 'antipsychotics' (such as pimozone).
- Narcotic painkillers.
- Sleeping tablets.
- Tranquilisers.
- Antihistamines that make you sleepy.
- Cimetidine - used to treat ulcers and heartburn.
- Erythromycin-used to treat infections.
- Beta blockers (such as nebivolol).
- Muscle relaxants.
- Omeprazole - used to treat the symptoms of acid reflux such as heartburn or acid regurgitation.
- Ticlopidine – a blood thinning medication used in people with an increased risk of stroke.
- Fluconazole - used in the treatment of fungal conditions.
- Dextromethorphan - used to relieve dry, irritating coughs
- Cannabidiol containing products (medicines, dietary supplements or recreational products).

Taking CLOCENT 10 with an opioid medicine (medicine to relieve pain) can depress your central nervous system.

Inform your doctor if you are currently taking any opioid medicine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist.

How to use CLOCENT 10

- How much to use

Adults

- The usual dose is 5mg to 80mg each day. If the dose is spread throughout

CLOCENT 10 Tablets BP

Clobazam 10mg

the day, the larger portion should be taken in the evening.

- Your doctor may increase or lower your dose to suit you.

Children (from 6 years of age)

- The usual start dose is 5mg daily. A maintenance dose of 0.3 to 1.0 mg/kg daily is usually sufficient.

Elderly

- The usual dose for anxiety is 10mg to 15mg each day

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Take CLOCENT 10 tablets at about the same time each day unless your doctor tells you otherwise. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the medicine.

Swallow the tablets whole, or crushed and mixed in apple purée. The tablets can be divided into equal halves of 5mg. CLOCENT 10 can be taken with or without food. If you are not sure when to consume it, ask your doctor or pharmacist.

- How long to use it

The duration of the treatment must be as short as possible. The doctor should assess your condition no more than two weeks for tension, agitation and anxiety treatment and no more than 4 weeks for epilepsy treatment after the start of treatment. The overall duration of treatments must not exceed 8 to 12 weeks. Your doctor may prolong your treatment period depending on your condition.

- If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- 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 use too much (overdose)

If you take more CLOCENT 10 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.

The following effects may happen: drowsiness, sleepiness, lack of voluntary muscle movements, breathing difficulty, low blood pressure, and rarely coma.

While you are using CLOCENT 10

- Things you must do

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Pregnancy and breast-feeding

Clobazam is not recommended during pregnancy or in women of childbearing potential not using contraception.

Women of childbearing potential should be informed about the benefits and risks using clobazam during pregnancy and should be instructed to contact their doctor about discontinuing clobazam if they become pregnant or plan to become pregnant. If treatment with clobazam is continued, the lowest effective dose should be used.

Cases of reduced fetal movement and variability in fetal heart rate have been described with the use of benzodiazepines during the second and third trimesters of pregnancy.

If clobazam is administered during the later stages of pregnancy or during childbirth, effects may occur in the newborn, such as respiratory depression (including respiratory distress and apnoea), signs of sedation, abnormally low body temperature, low muscle tone and feeding difficulties ('floppy infant syndrome'). Additionally, the children of mothers who used benzodiazepines long-term in the later stages of pregnancy may develop physical dependency, thus creating a risk of withdrawal symptoms after birth. Appropriate monitoring of the newborn in the postnatal period is recommended.

CLOCENT 10 must not be taken during breastfeeding because the active substance clobazam passes into breast milk

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give CLOCENT 10 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of Driving and using machines

CLOCENT 10 may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

CLOCENT 10 should be discontinued at the first sign of rash, unless the rash is clearly not related to the medicine.

Like all medicines, CLOCENT 10 can cause side effects, although not everybody gets them

Do not be alarmed by this list of possible side effects. You may possibly not facing any of these.

Tell your doctor immediately if you:

- Feeling restless, have difficulty sleeping or nightmares
- Feeling irritable or anxious
- Being aggressive
- Shaking fingers
- Believing things which are not true (delusions)
- Sensing things which are not there (hallucinations)*
- Feeling suicidal*

These side effects are more likely to happen in elderly people and children.

The following side effects may happen:

- Feeling sleepy or dizzy
- Dry mouth, constipation
- Reduced appetite, feeling sick

Other side-effects include:

- Severe skin reactions
- Headache
- Breathing problems
- Loss of memory, confusion
- Muscle weakness
- Problems walking or other movement problems
- Becoming dependent on CLOCENT 10 (also called 'physical or mental' dependence)

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

CLOCENT 10 Tablets BP

Clobazam 10mg

Storage and Disposal of CLOCENT 10

- Storage

Store below 30°C.

Keep out of reach of children.

- Disposal

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.

Product Description

- What it looks like

White to off white round tablets with break line and debossed with 'C' & '1' on one side and plain on other side.

- Ingredients

- Active ingredient(s)

Each Tablet contains, Clobazam Ph.Eur (10 mg)

- Inactive ingredients

Lactose monohydrate, Microcrystalline cellulose, Maize starch B, Purified Water, Starch 1500, Partially Pregelatinized maize starch, Colloidal silicon dioxide, Magnesium Stearate.

- MAL number(s):

MAL*****

Manufacturer

CENTAUR
PHARMACEUTICALS PVT.
LTD.

Plot No. 4, International Biotech Park,
Hinjewadi Phase II, Pune- 411057,
Maharashtra, INDIA.

Product Registration Holder

UNIMED SDN. BHD.
53, Jalan Tembaga SD5/2B, Bandar Sri
Damansara, 52200 Kuala Lumpur,
Malaysia.

Date of revision

22/01/2026

Serial Number

NPRA (R2) 24/156