1.3.2.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

QLOCAM 5 mg capsules

Clobazam

Contains sugar: Lactose monohydrate 141,85 mg

QLOCAM 10 mg tablets

Clobazam

Contains sugar: Lactose monohydrate 72,3 mg

Read all of this leaflet carefully before you start taking QLOCAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- QLOCAM 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 QLOCAM is and what it is used for
2. What you need to know before you take QLOCAM
3. How to take QLOCAM
4. Possible side effects
5. How to store QLOCAM
6. Contents of the pack and other information

1. What QLOCAM is and what it is used for

QLOCAM belongs to a group of medicines called benzodiazepines. It works by having a calming effect on the brain. QLOCAM can be used for:

- Relief of severe anxiety over a short time
- Relief of anxiety before an operation
- Relief of acute symptoms of alcohol withdrawal syndrome.

2. What you need to know before you take QLOCAM

Do not take QLOCAM if:

- you are hypersensitive (allergic) to benzodiazepines, or clobazam or any of the other ingredients of QLOCAM (listed in section 6).
- you have ever had problems with drugs or alcohol dependence in the past.
- you have a long-term (chronic) condition in which the muscles become weak and tire easily (myasthenia gravis).
- you have serious breathing problems (severe respiratory insufficiency).
- you stop breathing for short periods during sleep (sleep apnoea syndrome).
- you have liver problems.
- you are in the first three months of pregnancy or think you might be pregnant (see below, under Pregnancy, breastfeeding and fertility for more information).
- you are breastfeeding.
- the patient or your child is 3 years old or younger.

Warnings and precautions

Take special care with QLOCAM:

- If you are using anti-epileptic medication.

- If you have a serious skin reaction. Serious skin reactions have been seen when clobazam, as contained in QLOCAM, is taken with other medicines and may require stopping its use. Do not stop taking QLOCAM without first talking to your healthcare provider. A serious skin reaction can happen at any time during your treatment with QLOCAM, but is more likely to happen within the first 8 weeks of treatment. These skin reactions may need to be treated right away. Call your healthcare provider immediately if you have skin blisters, rash, sores in mouth, hives or any other allergic reaction.
- If you have a serious allergic reaction that may affect your skin or other parts of your body such as your liver, kidneys, heart, or blood cells. This allergic reaction can be life-threatening and can cause death, particularly if it is not treated as early as possible. Call your healthcare provider immediately if you have:
    - a skin rash
    - fever or swollen glands that do not go away
    - swelling of your face
    - shortness of breath
    - dark urine
    - yellowing of the skin or whites of the eyes.
- If you experience memory loss.
- If you drink alcohol as you should avoid drinking alcohol during treatment with QLOCAM, as this could increase the risk of the side effects of QLOCAM.
- If you have problems controlling your movements (spinal or cerebellar ataxia) or suffer from pre-existing muscle weakness.
- If you have depression, irrational fears and obsessions.

- QLOCAM can be addictive and cause withdrawal effects if treatment is stopped abruptly. Your doctor will prescribe QLOCAM for a limited duration and decrease your dosage gradually to prevent these withdrawal effects from happening.
- If you are sexually active and still of the age to conceive and are not using oral contraceptives.
- If you have shallow breathing (respiratory depression).
- If you have liver or kidney problems.
- If you are an elderly person as you may experience the side effects of QLOCAM more intense.
- If you have delusions (believing things which are not true) or hallucinations (sensing things which are not there).
- If you have ever become dependent upon another drug or alcohol.
- If you are using any other opioid type medications as this can lead to respiratory depression, coma, and death.
- If you are using other barbiturates, antihistamines, narcotics or other CNS depressants (see Other medicines and QLOCAM).

Children and adolescents

QLOCAM should not be used in children three years of age and younger.

Other medicines and QLOCAM

Always tell your healthcare 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 for epilepsy (such as phenytoin, carbamazepine or valproic acid).

- Medicines for depression such as MAOIs (monoamine oxidase inhibitors) or tricyclic antidepressants (such as amitriptyline).
- Medicines for severe mental illness called ‘neuroleptics’ (such as chlorpromazine, haloperidol and/or clozapine).
- Painkillers (medicines containing e.g. codeine, dihydrocodeine or morphine).
- Medicines used for sleep (such as zolpidem).
- Other tranquillisers (such as diazepam 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).
- If you are going to have an anaesthetic, tell your doctor or anaesthetist you are taking QLOCAM.

QLOCAM with food and alcohol

You should not use alcohol during treatment with QLOCAM (see Take special care with QLOCAM).

QLOCAM can be taken with food or without food.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

QLOCAM is expected to influence your ability to drive. You should not drive, use machinery or perform any tasks that require concentration until you are certain that QLOCAM does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent QLOCAM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which QLOCAM affects you (see section 4).

QLOCAM 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 medicinal product.

3. How to take QLOCAM

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

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

Each capsule/tablet should be swallowed whole, without chewing and with a glass of water.

The usual dose of QLOCAM is 10 mg to 30 mg each day. This can be taken as two separate doses or as a single dose at night.

Children (over 3 years old), the elderly, debilitated patients, as well as light-weight patients:

The daily dose will usually be half of the adult dose.

In people with kidney or liver problems:

The dosage will be determined by the prescribing doctor, as adjustments might be necessary.

Your doctor will tell you how long your treatment with QLOCAM will last. Do not stop treatment early because you can experience withdrawal symptoms.

If you have the impression that the effect of QLOCAM is too strong or too weak, tell your doctor or pharmacist.

If you take more QLOCAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs and symptoms of overdosage can be drowsiness, confusion, feeling very tired and weak and difficulty breathing.

If you forget to take QLOCAM

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

If you stop taking QLOCAM

Stopping QLOCAM can make you feel stressed (anxious), confused or depressed. You may also lose your appetite and have difficulty sleeping.

4. Possible side effects

QLOCAM can have side effects.

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

If any of the following happens, stop taking QLOCAM 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,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to QLOCAM. 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:

- feeling restless, have difficulty sleeping or nightmares,
- feeling irritable, quick to anger or anxious,
- believing things which are not true (delusions),
- sensing things which are not there (hallucinations),
- feeling suicidal. Discuss with your healthcare provider as treatment should be discontinued,
- difficulty breathing or shortness of breath,
- becoming dependent on QLOCAM (physical or mental dependence),
- yellow eyes and skin (jaundice), nausea, abdominal pain and swelling, and swelling of the legs.

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,
- the persistent feeling of sadness or loss of interest in normal daily tasks,
- reduced reaction to QLOCAM (especially during prolonged use),
- tiredness and sleepiness, sedation, dizziness, disturbance in attention, slowed or unclear speech,
- headache,
- tremor, loss of control of body movements (ataxia) or a fine tremor of the fingers may occur,
- dry mouth, constipation, nausea, vomiting,
- fatigue, especially at the beginning of treatment and when higher doses are used.

Less frequent side effects:

- abnormal behavior, confusional state,
- loss of libido (particularly with high doses or in long-term treatment, and is reversible),
- numbed emotions, have a lack of emotions (emotional poverty), decreased ability to remember new information (anterograde amnesia), inappropriate behaviour, memory impairment,
- eye problems such as double vision,
- weight gain,
- increased risk of falling.

Side effects with an unknown frequency:

- bleeding or bruising more easily than normal, nosebleeds, looking pale, fever, severe chills, sore throat or mouth ulcers,
- difficulty in staying awake or alert, reacting to things more slowly than usual, loss of memory, confusion,

- lack of interest and energy (lethargy),
- involuntary, rapid movement of one or both eyes (nystagmus),
- sensitivity to light,
- muscle spasms, muscle weakness,
- slow response to stimuli,
- abnormally low body temperature.

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. 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.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of QLOCAM.

5. How to store QLOCAM

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

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 QLOCAM contains

QLOCAM 5 mg capsules:

The active substance is clobazam 5 mg.

The other ingredients are:

Capsule content: Lactose monohydrate, magnesium stearate, pregelatinised starch, purified talc.

Capsule shell: Brilliant blue (E133), carmoisine (E122), gelatin, titanium dioxide (E171).

Printing ink: Black iron oxide (E172), potassium hydroxide (E525), propylene glycol (E1520), shellac (E904).

Contains sugar: Lactose monohydrate 141,85 mg

QLOCAM 10 mg tablets:

The active substance is clobazam 10 mg.

The other ingredients are:

Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, purified talc.

Contains sugar: Lactose monohydrate 72,3 mg

What QLOCAM looks like and contents of the pack

QLOCAM 5 mg is a white/blue opaque coloured, hard gelatin capsule of size "4", imprinted with "D98" on the cap with black ink, containing a white to off white powder.

QLOCAM 10 mg is a white to off white, round shaped tablet, scored on one side and debossed with "E 73" on the other side.

The tablet can be divided into equal halves.

10 capsules in white opaque PVC/PVdC/Aluminium blisters. 10 blister strips in a carton in pack sizes of 100 capsules.

10 tablets in white opaque PVC/Aclar/Aluminium blisters. 10 blister strips in a carton in pack sizes of 100 tablets.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

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Registration numbers

QLOCAM 5 mg: 51/2.6/0566

QLOCAM 10 mg: 51/2.6/0567

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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