1.3.1.1.2 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S5

1. NAME OF THE MEDICINE

QLOCAM 5 mg capsules

QLOCAM 10 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule of QLOCAM contains 5 mg clobazam.

Contains sugar: Lactose monohydrate 141,85 mg

Each tablet of QLOCAM contains 10 mg clobazam.

Contains sugar: Lactose monohydrate 72,3 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules:

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.

Tablets:

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.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

QLOCAM is indicated for:

- The treatment of anxiety in neurotic patients and for pre-operative medication. It may be effective in relieving the acute symptoms of alcohol withdrawal syndrome but has no specific usefulness in the treatment of psychotic patients.

QLOCAM is only indicated when the disorder is severe, disabling or subjecting the individual to extreme stress.

4.2. Posology and method of administration

Posology

Adults

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

Special populations

Elderly population and debilitated patients, as well as light-weight patients

Daily dose should be halved.

Increased responsiveness and higher susceptibility to adverse effects may be present in these patients and low initial doses and gradual dose increments, under careful observation, are required. Treatment should be started with the lowest recommended dose. The maximum dose should not be exceeded.

Dosage and duration of treatment must be adjusted to the indication, the severity of the condition and the individual clinical response. Due regard must be paid to the possibility of interference with alertness and reaction time. The fundamental principle is to keep the dose as low as possible.

Renal and hepatic impairment

Increased responsiveness and higher susceptibility to adverse effects may be present in these patients and require low initial doses and gradual dose increments under careful observation (see section 4.4).

Paediatric population

Daily dose should be halved.

Increased responsiveness and higher susceptibility to adverse effects may be present in these patients and low initial doses and gradual dose increments, under careful observation, are required. Treatment should be started with the lowest recommended dose. The maximum dose should not be exceeded.

Dosage and duration of treatment must be adjusted to the indication, the severity of the condition and the individual clinical response. Due regard must be paid to the possibility of interference with alertness and reaction time. The fundamental principle is to keep the dose as low as possible.

QLOCAM must not be used in children of age 3 years and younger (see section 4.3).

Secondary dose adjustment

After improvement of symptoms, the dose may be reduced.

Duration of treatment

The duration of treatment should be as short as possible. The patient should be reassessed after a period, not exceeding 4 weeks, and regularly thereafter in order to evaluate the need for continued treatment, especially where the patient is free of symptoms. The overall duration of treatment generally should not be more than 8 to 12 weeks, including a tapering off process. In certain cases, extension beyond the maximum treatment period may be necessary. If so, it should not take place without re-evaluation of the patient's status, using special expertise. It is strongly recommended that prolonged periods of uninterrupted treatment be avoided, since it may lead to dependence (see section 4.4).

Discontinuation of treatment

It is strongly recommended that after prolonged treatment, QLOCAM is not withdrawn suddenly, but rather that the dose is reduced gradually under medical supervision; otherwise, withdrawal symptoms may occur (see section 4.4).

Method of administration

For oral administration.

The capsules are to be swallowed without chewing with a generous amount of liquid (approximately 1 glass).

QLOCAM can be given with or without food.

4.3. Contraindications

QLOCAM is contraindicated in:

- Patients with hypersensitivity to clobazam, benzodiazepines or to any excipients in QLOCAM (see section 6.1).
- Patients with any history of drug or alcohol dependence (increased risk of development of dependence).
- Patients with myasthenia gravis (risk of aggravation of muscle weakness).
- Patients with severe respiratory insufficiency (risk of deterioration).
- Patients with sleep apnoea syndrome (risk of deterioration).
- Patients with severe impairment of liver function (risk of precipitating encephalopathy).
- During the first trimester of pregnancy (see section 4.6 for use during second and third trimester).
- Breastfeeding women (see section 4.6).
- Benzodiazepines must not be given to children without careful assessment of the need for their use. QLOCAM must not be used in children of age 3 years and younger.

4.4. Special warnings and precautions for use

Hypersensitivity

Serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with clobazam, a contained in QLOCAM, in both children and adults during the post- marketing experience. A majority of the reported cases involved the concomitant use of other medicines, including anti-epileptic medicines that are associated with serious skin reactions.

SJS/TEN could be associated with a fatal outcome. Patients should be closely monitored for signs or symptoms of SJS/TEN, especially during the first 8 weeks of treatment. Clobazam, as contained in QLOCAM, should be immediately discontinued when SJS/TEN is suspected. If signs or symptoms suggest SJS/TEN, use of this medicine should not be resumed and alternative therapy should be considered (see section 4.8).

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including clobazam, as contained in QLOCAM. These events can be fatal or life-threatening, particularly if diagnosis and treatment do not occur as early as possible. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately.

QLOCAM should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Amnesia

Anterograde amnesia may occur even if benzodiazepines, such as QLOCAM, are used in normal dose range, but especially at higher dose levels. In case of loss or bereavement psychological adjustment may be inhibited by benzodiazepines.

Muscle weakness

Clobazam, as contained in QLOCAM, can cause muscle weakness. Therefore, in patients with pre-existing muscle weakness or spinal or cerebellar ataxia or sleep apnoea, special observation is required, and a dose reduction may be necessary.

Clobazam, as contained in QLOCAM, is contraindicated in patients with myasthenia gravis (see section 4.3).

Depression and personality disorders

Disinhibiting effects may be manifested in various ways. Suicide may be precipitated in patients who are depressed and aggressive behaviour towards self and others may be precipitated.

Extreme caution should therefore be used in prescribing benzodiazepines in patients with personality disorders.

Dependence

Benzodiazepines, including clobazam as contained in QLOCAM, may lead to physical and psychological dependence. The risk of dependence increases with the dose and duration of treatment. However, this risk is present even with daily intake of QLOCAM over periods of only

a few weeks and applies not only to possible abuse with particularly high doses but also to the therapeutic dose range. The risk of dependence is increased in patients with a history of alcohol or drug abuse. Therefore, the duration of treatment should be as short as possible (see section 4.2). The therapeutic benefit must be balanced against the risk of dependence during prolonged use.

Rebound phenomena are characterised by a recurrence in enhanced form of the symptoms which originally led to QLOCAM treatment. This may be accompanied by other reactions including mood changes, anxiety or sleep disturbances and restlessness.

Since the risk of withdrawal phenomena/rebound phenomena is greater after abrupt discontinuation of treatment it is recommended that the dosage be decreased gradually.

Once physical dependence has developed, abrupt termination of QLOCAM treatment will lead to withdrawal symptoms. These may include headaches, sleep disturbances, extreme anxiety, tension, restlessness, confusion, excitability and irritability.

In severe cases the following symptoms may occur: derealisation, depersonalisation, hallucinations and symptomatic psychoses (e.g. withdrawal delirium), numbness and tingling sensations in the extremities, muscle pain, tremor, sweating, nausea, hyperacusis, hypersensitivity to light, noise and physical contact, as well as epileptic seizures.

A withdrawal syndrome may also occur when abruptly changing over from a benzodiazepine with a long duration of action (for example QLOCAM) to one with a short duration of action (see section 4.2).

Pregnancy

Clobazam, as contained in QLOCAM, is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception (see section 4.3).

Respiratory depression

Respiratory function should be monitored in patients with chronic or acute severe respiratory insufficiency and a dose reduction of clobazam may be necessary. Clobazam, as contained in QLOCAM, is contraindicated in patients with severe respiratory insufficiency (see section 4.3).

Renal and hepatic impairment

In patients with impairment of renal or hepatic function, responsiveness to clobazam, as contained in QLOCAM, and susceptibility to adverse effects are increased, and a dose reduction may be necessary. In long-term treatment renal and hepatic function must be checked regularly (see section 4.2).

Elderly patients

In the elderly, due to the increased sensitivity to adverse reactions such as drowsiness, dizziness and muscle weakness, there is an increased risk of fall that may result in serious injury. A dose reduction is recommended (see section 4.2).

Tolerance in epilepsy

In the treatment of epilepsy with benzodiazepines, including clobazam, as contained in QLOCAM, consideration must be given to the possibility of a decrease in anti-convulsant efficacy (development of tolerance) during the course of treatment.

CYP2C19 poor metabolisers

In patients who are CYP2C19 poor metabolisers, levels of the active metabolite N-desmethylclobazam are expected to be increased as compared to extensive metabolisers. As this may lead to increased side effects, dosage adjustment of clobazam, as contained in

QLOCAM, may be necessary (e.g. low starting dose with careful dose titration) (see section 5.2).

Alcohol

It is recommended that patients abstain from drinking alcohol during treatment with QLOCAM, as there is an increased risk of sedation and other adverse effects (see section 4.5).

Concomitant use of opioids and benzodiazepines

Concomitant use of opioids and benzodiazepines, including clobazam, as contained in QLOCAM, may result in sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of opioids and benzodiazepines for use in patients for whom alternative treatment options are inadequate.

If a decision is made to prescribe clobazam, as contained in QLOCAM concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use, and follow patients closely for signs and symptoms of respiratory depression and sedation (see section 4.5).

QLOCAM is not recommended for the primary treatment of psychotic illness. In patients with depression or anxiety associated with depression, QLOCAM must be used only in conjunction with adequate concomitant treatment. Use of benzodiazepines (such as QLOCAM) alone, can precipitate suicide in such patients (see section 4.1).

Before treatment of anxiety states associated with emotional instability it must first be determined whether the patient suffers from a depressive disorder requiring adjunctive or different treatment.

Schizophrenia or other psychotic illnesses

In patients with schizophrenic or other psychotic illnesses, use of benzodiazepines is recommended only for adjunctive treatment, i.e. not for primary treatment (see section 4.1).

Barbiturates, antihistamines, narcotics or other CNS depressants

For patients receiving barbiturates, antihistamines, narcotics or other central nervous system depressants, there is an additive risk of central nervous system depression when these medicines are taken together. Large doses may produce syncope.

Duration of treatment

The duration of treatment should be as short as possible (see section 4.2) but should not exceed 8 to 12 weeks in case of anxiety, including the tapering-off process. Extension beyond these periods should not take place without re-evaluation of the situation. It may be useful to inform the patient when treatment is started that it will be of limited duration and to explain precisely how the dosage will be progressively decreased. Moreover, it is important that the patient should be aware of the possibility of rebound phenomena, thereby minimising anxiety over such symptoms, should they occur while the product is being discontinued.

Excipients

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5. Interaction with other medicines and other forms of interaction

Alcohol

Concomitant consumption of alcohol can increase the bioavailability of clobazam, as contained in QLOCAM by 50 % (see section 5.2) and therefore lead to increased clobazam effects (see section 4.4).

Central nervous system (CNS) depressant medicines

Especially when QLOCAM is administered in higher doses, a mutually potentiating effect is to be expected if other CNS depressant medicines (such as antipsychotics, anxiolytics, certain antidepressant agents, anticonvulsant medicines, sedative antihistamines, anaesthetics, hypnotics or narcotic analgesics, or other sedatives) are taken at the same time. Special caution is also necessary when QLOCAM is administered in cases of intoxication with such substances or with lithium.

Anticonvulsants

If QLOCAM is administered simultaneously with anticonvulsants, the dosage must be adjusted under regular medical supervision (EEG monitoring), as there may be interactions with the patient's anticonvulsant medicine.

Valproic acid

In patients receiving concomitant treatment with valproic acid, there may be a slight to moderate rise in plasma valproic acid concentration.

Carbamazepine and phenytoin

Phenytoin plasma levels may rise if patients receive concomitant treatment with QLOCAM.

Where possible, it is recommended that blood levels of concomitantly administered valproic acid or phenytoin be monitored. Carbamazepine and phenytoin may increase the metabolic conversion of clobazam, as contained in QLOCAM, to the active metabolite *N*-desmethylclobazam.

Stiripentol

Stiripentol increases plasma levels of clobazam, as contained in QLOCAM, and its active metabolite, *N*-desmethylclobazam, through inhibition of CYP3A and CYP2C19. Monitoring of blood levels is recommended, prior to initiation of stiripentol and then once new steady-state concentration has been reached, i.e. after approximately 2 weeks.

Narcotic analgesics

If QLOCAM is used concomitantly with narcotic analgesics, possible euphoria may be enhanced; this may lead to increased psychological dependence.

Muscle relaxants

The effects of muscle relaxants and nitrous oxide may be enhanced.

CYP2C19 inhibitors

Strong and moderate inhibitors of CYP2C19 may result in increased exposure to *N*-desmethylclobazam (N-CLB), the active metabolite of clobazam, as contained in QLOCAM. Dosage adjustment of QLOCAM may be necessary when co-administered with strong (e.g., fluconazole, fluvoxamine, ticlopidine) or moderate (e.g. omeprazole) CYP2C19 inhibitors (see section 5.2).

CYP2D6 substrates

Clobazam, as contained in QLOCAM, is a weak CYP2D6 inhibitor (see section 5.2). Dose adjustment of medicines metabolised by CYP2D6 (e.g. dextromethorphan, pimozide, paroxetine, nebivolol) may be necessary.

Opioids

The concomitant use of sedative medicines such as benzodiazepines or related medicines such as QLOCAM with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4).

4.6. Fertility, pregnancy and lactation

QLOCAM should be used judiciously during pregnancy and preferably avoided (see section 4.3).

Women of childbearing potential / Contraception in males and females

Clobazam, as contained in QLOCAM is not recommended during pregnancy and in women of childbearing potential not using contraception. Women of childbearing potential should be informed of the risks and benefits of the use of clobazam during pregnancy.

If a woman plans a pregnancy or becomes pregnant, carefully evaluate the risks and benefits and whether treatment with clobazam should be discontinued. If clobazam treatment is to be continued, use clobazam at the lowest effective dose (see section 4.2).

Pregnancy

Administration of QLOCAM before or during childbirth can result in the occurrence of respiratory depression (including respiratory distress and apnoea), which may be associated with other disorders such as signs of sedation, hypothermia, hypotonia, feeding difficulties in the newborn and an increase in foetal heart rate (signs and symptoms of the so-called "floppy infant syndrome"). Moreover, infants born to mothers who have taken benzodiazepines over longer periods during the later stages of pregnancy may have developed physical dependence and may be at risk of developing a withdrawal syndrome in the postnatal period. Appropriate monitoring of the newborn in the postnatal period is recommended.

Generally, QLOCAM must not be used in the first trimester of pregnancy (see section 4.3). In the later stages of pregnancy, it must only be used if there are compelling indications.

Breastfeeding

QLOCAM must not be used in breastfeeding women, since it passes into breast milk (see sections 4.3 and 5.2).

Clobazam, as contained in QLOCAM crosses the placental barrier and appears in breast milk. Both in the foetal blood and in breast milk, effective concentrations may be reached.

Fertility

No clinical data on fertility are available. In a fertility study in male and female rats no effect on fertility was observed (see section 5.3).

4.7. Effects on ability to drive and use machines

QLOCAM has a major influence on the ability to drive or operate machinery.

Since adverse reactions such as sedation and muscle weakness have been reported in patients receiving QLOCAM, patients should not drive, use machinery or perform any tasks

that require concentration, until they are certain that QLOCAM does not adversely affect their ability to do so (see section 4.4 and/or 4.8).

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Blood and the lymphatic system disorders			Blood dyscrasias
Metabolism and nutrition disorders	Decreased appetite	Weight gain (particularly with high doses or in long- term treatment, and is reversible)	
Psychiatric disorders	Irritability, aggressiveness, restlessness, depression (pre-existing depression may be unmasked), medicine tolerance (especially during prolonged use) (see section 4.4), acute agitation	Abnormal behaviour, confusional state, anxiety, delusion, nightmare, loss of libido (particularly with high doses or in long-term treatment, and is reversible), numbed emotions, emotional poverty	Dependence (especially during prolonged use) (see section 4.4), initial insomnia, anger, fits of rage, hallucination, psychotic disorder, poor sleep quality, difficulty in falling asleep or sleeping through suicidal ideation or tendencies
Nervous system disorders	Tiredness and sleepiness (somnolence), especially at the beginning of treatment and when higher doses are used, sedation, dizziness, disturbance in attention, slowed or indistinct speech (disorders of articulation), (particularly with high doses or in long-term treatment, and is reversible), headache, tremor, ataxia or a fine tremor of the fingers may occur	Anterograde amnesia may occur even if benzodiazepines are used in the normal dose range, but especially at higher dose levels, amnesia effects may be associated with inappropriate behaviour, memory impairment	Slowed reaction time, drowsiness*, disorientation and confusion, lethargy, cognitive disorder, impairment of consciousness (sometimes combined with respiratory disorders, may occur in very rare cases, particularly in elderly patients; these effects sometimes persist for a considerable length of time), nystagmus (particularly with high doses or in long-term treatment), unsteadiness of gait and other motor functions (such reactions occur particularly with high doses or in long-term treatment, and are reversible).
Eye disorders		Visual disorders (diplopia). Such reactions occur particularly with high doses or in long-term treatment and are reversible	

Respiratory, thoracic and mediastinal disorders			Respiratory depression, respiratory failure
Gastrointestinal disorders	Dry mouth, constipation, nausea/vomiting		
Hepatobiliary disorders			Hepatic dysfunction
Skin and subcutaneous tissue disorders		Cutaneous reactions, such as rash may develop	Photosensitivity reactions, urticaria, Stevens-Johnson syndrome, toxic epidermal necrolysis (including some cases with fatal outcome), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity
Musculoskeletal and connective tissue disorders			Muscle spasms, muscle weakness
General disorders and administrative site conditions	Fatigue, especially at the beginning of treatment and when higher doses are used		Slow response to stimuli, hypothermia
Injury, poisoning and procedural complications		Fall	

*Drowsiness is more common in elderly and debilitated patients and in patients receiving high doses.

b) Description of selected adverse reactions

Respiratory disorders

Respiratory depression and respiratory failure have been reported especially if administered in high doses. Therefore, particularly in patients with pre-existing compromised respiratory function (e.g. in patients with bronchial asthma) or brain damage, respiratory insufficiency may occur or deteriorate.

Psychiatric disorders

Pre-existing depression may be unmasked during benzodiazepine use. Tolerance and dependence may develop, especially during prolonged use (see section 4.4). In the event of initial insomnia, anger, fits of rage, hallucination, psychotic disorder, poor sleep quality, difficulty in falling asleep or sleeping through suicidal ideation or tendencies, treatment with QLOCAM must be discontinued.

Discontinuation of the therapy may result in withdrawal or rebound phenomena (see section 4.4). Abuse of benzodiazepines has been reported.

When used as an adjuvant in the treatment of epilepsy, this preparation may in rare cases cause restlessness and muscle weakness.

As with other benzodiazepines, the therapeutic benefit must be balanced against the risk of habituation and dependence during prolonged use.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions 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

4.9. Overdose

Symptoms

Overdose and intoxication with benzodiazepines, including QLOCAM, may lead to central nervous system depression, associated with drowsiness, confusion and lethargy, possibly

progressing to ataxia, respiratory depression, hypotension and, rarely, coma. The risk of a fatal outcome is increased in cases of combined poisoning with other CNS depressants, including alcohol.

Treatment

In treatment for intoxication, it is recommended that the possible involvement of multiple agents be taken into consideration. Intravenous fluid replenishment and general supportive measures may be indicated in addition to monitoring of consciousness, respiration, pulse rate and blood pressure.

Secondary elimination of QLOCAM (by forced diuresis or haemodialysis) is ineffective.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A. 2.6 Tranquillisers

Pharmacotherapeutic group: Benzodiazepine derivatives

ATC code: N05BA09

Mechanism of action

Clobazam is a 1,5-benzodiazepine, with anxiolytic properties.

5.2. Pharmacokinetic properties

Absorption

After oral administration, clobazam is well-absorbed. Relative bioavailability of clobazam capsules, tablets or solution (in propylene glycol) was not significantly different.

Time to peak plasma concentration (T_{max}) is achieved from 0,5 to 4 hours. The administration of clobazam tablets with food slows the rate of absorption by approximately 1 hour but does not affect the overall extent of absorption.

Concomitant intake of alcohol can increase the bioavailability of clobazam by 50 % (see section 4.5).

Distribution

After a single dose of 20 mg clobazam, marked interindividual variability in maximum plasma concentrations (222 to 709 ng/mL) was observed after 0,25 to 4 hours. Clobazam is lipophilic and distributes rapidly throughout the body. Based on a population pharmacokinetic analysis, the apparent volume of distribution at steady state was approximately 102 L and is concentration independent over the therapeutic range.

Approximately 80 to 90 % of clobazam is bound to plasma protein.

Clobazam accumulates approximately 2 to 3-fold to steady-state while the active metabolite N- desmethylclobazam (N-CLB) accumulates approximately 20-fold following clobazam twice-daily administration. Steady-state concentrations are reached within approximately 2 weeks.

Biotransformation

Clobazam is rapidly and extensively metabolised in the liver. Clobazam metabolism occurs primarily by hepatic demethylation to N-desmethylclobazam (N-CLB), mediated by CYP3A4 and to a lesser extent by CYP2C19. N-CLB is an active metabolite and the main circulating metabolite found in human plasma. N-CLB undergoes further biotransformation in the liver to form 4-hydroxy-N-desmethylclobazam, primary mediated by CYP2C19.

CYP2C19 poor metabolisers exhibit a 5-fold higher plasma concentration of N-CLB compared to extensive metabolisers.

Clobazam is a weak CYP2D6 inhibitor. Co-administration with dextromethorphan led to increases of 90 % in AUC and 59 % in C_{max} values for dextromethorphan.

Elimination

Based on a population pharmacokinetic analysis, plasma elimination half-lives of clobazam and N-CLB were estimated to be 36 hours and 79 hours, respectively. Clobazam is cleared mainly by hepatic metabolism with subsequent renal elimination. In a mass balance study, approximately 80 % of the administered dose was recovered in urine and about 11 % in the faeces.

Less than 1 % of unchanged clobazam and less than 10 % of unchanged N-CLB are excreted through the kidneys.

Special population

Elderly patients

In the elderly, there is a tendency to a reduction in clearance

following oral administration; terminal half-life is prolonged, and the distribution volume increased. This may lead to a more extensive accumulation of the medicine, when administered on a multiple-dose basis than in younger subjects. The effect of age on the clearance and accumulation profile of clobazam seems also to apply to the active metabolite.

Hepatic impairment

In patients with severe liver disease, the distribution volume of clobazam is increased and the terminal half-life is prolonged.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

QLOCAM 5 mg capsules

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 glycolcol (E1520), shellac (E904).

QLOCAM 10 mg tablets

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

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25 °C.

6.5. Nature and contents of container

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.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBERS

QLOCAM 5 mg: 51/2.6/0566

QLOCAM 10 mg: 51/2.6/0567

9. DATE OF FIRST AUTHORISATION

19 March 2024

10. DATE OF REVISION OF TEXT

25 March 2025

Die Afrikaanse Professionele Inligting is op versoek beskikbaar.

Mediese Blitslyn: 0800 118 088.

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