PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

CLOZYD 10 mg tablets

Clobazam

Contains sugar (72,3 mg lactose monohydrate per tablet)

CLOZYD 20 mg tablets

Clobazam

Contains sugar (144,6 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking CLOZYD.

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

1. What CLOZYD is and what it is used for

CLOZYD contains the active ingredient clobazam.

This belongs to a group of medicines called benzodiazepines. It works by having a calming effect on the brain.

CLOZYD can be used for:

- Severe anxiety, over a short period of time.
- Relieving the short-term (acute) symptoms of alcohol withdrawal syndrome (effects experienced when a person stops consuming alcohol).

2. What you need to know before you take CLOZYD

Do not take CLOZYD:

- If you are hypersensitive (allergic) to benzodiazepines, clobazam or any of the other ingredients of CLOZYD (listed in section 6).
- If you have ever had problems with drugs or alcohol dependence in the past.
- If you have a long-term (chronic) condition in which your muscles become weak and tire easily (myasthenia gravis).
- If you have serious breathing problems (severe respiratory insufficiency).
- If you stop breathing for short periods during sleep (sleep apnoea syndrome).
- If you have serious liver problems (yellow skin and eyes or dark urine).
- If 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).
- If you are breastfeeding your baby.
- If the patient or your child is 3 years old or younger.

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

Warnings and precautions

Take special care with CLOZYD:

- If you experience memory loss (forgetfulness).
- 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 chronic or acute breathing problems.
- If you experience any skin reactions during treatment with CLOZYD.
- If you have ever become dependent upon another drug or alcohol (alcohol should not be taken during treatment with CLOZYD as there is an increased risk of experiencing side effects).
- If you are over 65 years old (this is due to the increased sensitivity to adverse reactions in elderly patients such as drowsiness, dizziness and muscle weakness and also an increased risk of fall, that may result in serious injury).
- If you have kidney or liver problems.
- If you have difficulty digesting medicines (your liver may not metabolise [break down] medicines adequately, causing the medicine to remain in your body for a longer period of time, resulting in side effects).
- If you are taking any medicinal or non-medicinal products containing cannabidiol, as it may increase the side effects of clobazam.

Drowsiness, difficulty breathing, coma and death may occur if CLOZYD is taken together with opioids. CLOZYD and opioids should only be used concomitantly when other treatment options are inadequate. Please tell your doctor about all opioid medicines you are taking and follow your doctor’s dosage recommendations closely.

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including CLOZYD. However, it has not been established whether this is caused by CLOZYD or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice (see section 4).

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

Other medicines and CLOZYD

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

Inform your doctor if you are taking any of the following:

- Medicines for epilepsy (such as phenytoin, carbamazepine, stiripentol or valproic acid). Addition of CLOZYD to established anticonvulsant medicine may cause a change in plasma levels of these medicines. If used as an adjuvant in epilepsy, the dosage of CLOZYD should be determined by monitoring the electroencephalogram (EEG) and the plasma levels of the other medicines should be checked. Clinical monitoring is recommended and dose adjustment may be necessary.
- Medicines for depression (such as monoamine oxidase inhibitors [MAOIs] or tricyclic antidepressants such as trazodone, or selective serotonin re-uptake inhibitors [SSRIs] such as fluvoxamine or paroxetine). Dose adjustment of CLOZYD may be necessary when co-administered with strong CYP2C19 inhibitors, e.g. fluvoxamine.
- Medicines for severe mental illness called “antipsychotics” (such as chlorpromazine, haloperidol, clozapine and pimozide). Dose adjustment of medicines metabolised by CYP2D6, e.g. pimozide, may be necessary.
- Painkillers (such as medicines containing codeine, dihydrocodeine or morphine). The concomitant use of CLOZYD and opioids increases the risk of sedation (sleepiness), respiratory depression (difficulty breathing), coma and death because of additive central nervous system (CNS) depressant effects. Limit dosage and duration of concomitant use of CLOZYD and opioids.
- Sleeping tablets (such as zolpidem) or tranquillisers (such as diazepam, temazepam or lorazepam). An enhancement of the central depressive effect may occur, especially when CLOZYD is administered at higher doses, in combination with antipsychotics, hypnotics, anxiolytics, sedatives, antidepressant medicines, narcotic analgesics, anticonvulsant medicines and anaesthetics.
- Muscle relaxants (such as baclofen). The effects of muscle relaxants may be enhanced.
- Antihistamines that make you sleepy (such as chlorphenamine, promethazine or

diphenhydramine). An enhancement of the central depressive effect may occur, especially when CLOZYD is administered at higher doses, in combination with sedative antihistamines.

- Lithium – used for a mental illness called manic-depressive illness (mood changes between a state of high excitability or exaggerated emotions, and depression). Special caution is also necessary when CLOZYD is administered in cases of overdosage with lithium. An enhancement of the central depressive effect may occur, especially when CLOZYD is administered at higher doses, in combination with lithium.
- Omeprazole – used to treat stomach ulcers or heartburn. Dosage adjustment of CLOZYD may be necessary when co-administered with moderate CYP2C19 inhibitors (e.g. omeprazole).
- Ticlopidine – an antiplatelet medicine used to prevent blood clots. Dosage adjustment of CLOZYD may be necessary when co-administered with strong CYP2C19 inhibitors (e.g. ticlopidine).
- Fluconazole – used in the treatment of fungal conditions. Dose adjustment of CLOZYD may be necessary when co-administered with strong CYP2C19 inhibitors (e.g. fluconazole).
- Dextromethorphan – used to relieve dry, irritating coughs. Dose adjustment of medicines metabolised by CYP2D6 (e.g. dextromethorphan) may be necessary.
- Nebivolol – used to treat high blood pressure. Dose adjustment of medicines metabolised by CYP2D6 (e.g. nebivolol) may be necessary.
- Cannabidiol-containing products (medicinal or non-medicinal products). Concomitant use of cannabidiol and CLOZYD increases the incidence of somnolence (sleepiness) and sedation. A dose reduction of CLOZYD should be considered if somnolence or sedation is experienced when CLOZYD is co-administered with cannabidiol.

Concomitant use of CLOZYD and opioids increases the risk of drowsiness, difficulty breathing, coma and death. Follow your doctor’s dosage recommendations closely.

If you are going to have an operation and receive an anaesthetic, tell your doctor or anaesthetist that you are taking CLOZYD. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants to give you.

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

CLOZYD with food, drink and alcohol

You should not consume alcohol during treatment with CLOZYD (see **Take special care with CLOZYD**).

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 CLOZYD.

Do not take CLOZYD if you are:

- In the first three months of pregnancy.
- Breastfeeding, since CLOZYD passes into the breast milk.

Pregnancy

The use of CLOZYD is not recommended during pregnancy and in women of childbearing potential not using contraception.

If you discover that you are pregnant or are planning to have a baby, consult your doctor immediately to reassess the need for treatment. Do not stop taking CLOZYD without talking to your doctor.

A large amount of data has not shown evidence for malformations associated with the use of benzodiazepines. However, some studies have shown a potentially increased risk of cleft lip and palate in newborn babies compared to that in the general population. Cleft lip and palate (sometimes called “harelip”) is an inborn deformation caused by incomplete fusion of the palate and upper lip.

Reduced fetal movement and fetal heart rate variability may occur after taking CLOZYD during the second and/or third trimester of pregnancy.

If CLOZYD is taken at the end of pregnancy or during childbirth, your baby may show drowsiness (sedation), muscle weakness (hypotonia or floppy infant syndrome), a drop in body temperature (hypothermia), difficulty feeding (problems suckling causing poor weight gain) and breathing problems (respiratory depression, sometimes severe).
If taken regularly in late pregnancy, your baby may get withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Breastfeeding

Do not take CLOZYD if you are breastfeeding or are planning to breastfeed. This is because it may pass into the mothers' milk.

Driving and using machines

CLOZYD may cause sleepiness, concentration and memory problems or visual disturbances (see section 4). It is not always possible to predict to what extent CLOZYD may interfere with your daily activities. Do not drive a vehicle or operate any tools until you know how CLOZYD will affect you.

CLOZYD contains lactose monohydrate

If you have been told by your doctor that you cannot tolerate some sugars, tell your doctor before taking CLOZYD.

3. How to take CLOZYD

Do not share medicines prescribed for you with any other person.
Always take CLOZYD exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.
Your doctor will tell you how long your treatment with CLOZYD will last. Do not stop treatment early or abruptly because you may experience serious side effects.

Taking CLOZYD

The 10 mg tablets can be divided into equal halves of 5 mg.

The 20 mg tablets can be divided into equal halves of 10 mg.

The tablets are to be swallowed with a generous amount of liquid (approximately 1 glass).

CLOZYD can be taken with or without food.

Adults

Your doctor will decide on the dose you should take.

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

Your doctor may lower the dose to suit you.

Elderly patients, debilitated patients, children (over 3 years old) and patients with a low body mass

Your daily dosage should be halved.

Patients with kidney or liver problems

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

Duration of treatment

CLOZYD is usually given for 2 to 4 weeks. After that, your doctor will decide whether you should continue your treatment.

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

Your doctor will tell you how long your treatment with CLOZYD will last.

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

If you take more CLOZYD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any CLOZYD tablets left or not.

If you forget to take CLOZYD

If you forget to take 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 forgotten individual doses.

If you stop taking CLOZYD

Do not stop taking CLOZYD unless your doctor tells you to. Should you need to stop taking CLOZYD, your doctor will decide which is the best method for you.

If your doctor says that you can stop taking CLOZYD, you need to do this gradually. Your doctor will help you to do this.

If you stop taking CLOZYD tablets suddenly, it 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 CLOZYD, ask your doctor or pharmacist.

4. Possible side effects

CLOZYD can have side effects.

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

other health care provider for advice.

If any of the following happens, stop taking CLOZYD 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOZYD. 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 or anxious.
- Believing things which are not true (delusions).
- Sensing things which are not there (hallucinations).
- Feeling suicidal.

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

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 if you notice any of the following:

Frequent side effects

- Difficulty in staying awake or alert.
- Feeling tired, sleepy or dizzy.
- Feeling agitated or being aggressive.
- Depression.
- Headache.
- Short attention span.
- Difficulty in speaking.
- Shaking fingers (tremor).

- Problems with walking or other movement problems.
- Having less effect than normal (especially in long-term use).
- Dry mouth, constipation.
- Loss of appetite, feeling sick (nausea) or being sick (vomiting).

Less frequent side effects

- Loss of sexual drive.
- Memory difficulties, confusion.
- Emotional numbness (feeling empty or dead inside, and not caring about anything).
- Double vision.
- Skin rash.
- Increased body mass.
- Anxiety (a feeling of fear, dread and uneasiness).
- Delusions (having false or unrealistic beliefs or opinions).
- Nightmares.
- Fall.

Side effects with an unknown frequency

- Blood disorders (affect red blood cells, white blood cells or platelets).
- Becoming dependent on CLOZYD (physical or mental dependence, especially in long-term use).
- Cognitive disorder (disorders that affect cognitive abilities including learning, memory, perception and problem solving).
- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis).
- Feeling angry.
- Breathing problems.
- Liver problems.
- Sensitivity to sunlight.

- Itchy, lumpy rash (urticaria).
- Muscle spasms or muscle weakness.
- Reacting to things more slowly than usual.
- Disorientation (when you are confused about the time, where you are or even who you are).
- Rapid uncontrollable movement of the eyes.
- Learning problems.
- 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 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 CLOZYD.

5. How to store CLOZYD

- Store at or below 25 °C.
- Keep tablets in original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLOZYD contains

The active substance is clobazam.

Other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, maize starch and talc.

What CLOZYD looks like and contents of the pack

CLOZYD 10:

White to off-white, modified, capsule shaped, biconvex tablet, debossed with “13” and “25” on either side of functional scoreline on one side and plain on other side. The tablet should be free of all physical defects.

CLOZYD 20:

White to off-white, modified, capsule shaped, biconvex tablet, debossed with “13” and “26” on either side of functional scoreline on one side and plain on other side. The tablet should be free of all physical defects.

Opaque white 60 mL HDPE bottle, with a 33 mm child-resistant closure, inserted into an outer cardboard carton.

Pack size: 100 tablets.

Silver aluminium foil/clear transparent PVC/PVdC blister strip (containing 10 x 10 tablets), inserted into an outer cardboard carton.

Pack size: 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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