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| <b>Applicant:</b> Oethmaan Biosims (Pty) Ltd   | <b>Date of SAHPRA approval</b><br>02 August 2022  |
| <b>Product:</b><br>CLOZAPINE 25 mg OETHMAAN<br>CLOZAPINE 50 mg OETHMAAN<br>CLOZAPINE 100 mg OETHMAAN | <b>Dosage form and strength:</b><br>Each tablet contains: 25 mg/50 mg/100 mg<br>clozapine |

## PATIENT INFORMATION LEAFLET - CLEAN

### INFORMATION LEAFLET

#### SCHEDULING STATUS:

**S5**

**CLOZAPINE 25 OETHMAAN, tablet**

**CLOZAPINE 50 OETHMAAN, tablet**

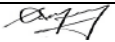
**CLOZAPINE 100 OETHMAAN, tablet**

**Clozapine**

**Contains sugar (lactose monohydrate)**

**Read all of this leaflet carefully before you are given CLOZAPINE OETHMAAN.**

- 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.

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- CLOZAPINE OETHMAAN 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.

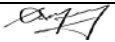
### What is in this leaflet

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

#### 1. What CLOZAPINE OETHMAAN is and what it is used for

CLOZAPINE OETHMAAN contains a medicine called clozapine which belongs to a group of medicines called antipsychotics (medicines that are used to treat specific mental disorders such as psychosis). CLOZAPINE OETHMAAN is used:

- To treat the symptoms of severe schizophrenia (a mental disorder), in people who have not responded to other medications.
- To help reduce the risk of suicidal behaviour in people with schizophrenia or similar disorders.

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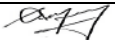
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- To treat the symptoms of any mental disorders caused by medicines used in treating Parkinson's disease.

## 2. What you need to know before you are given CLOZAPINE OETHMAAN

### Do not take CLOZAPINE OETHMAAN if:

- you are hypersensitive (allergic) to clozapine or any of the other ingredients of CLOZAPINE OETHMAAN (listed in **See what CLOZAPINE OETHMAAN contains** below).
- you have the following conditions:
  - are not able to have regular blood tests
  - if you have ever been told you have a low white blood cell count (e.g. leukopenia or agranulocytosis), especially if this was caused by medicines. This does not apply if you have had low white blood cell count caused by previous chemotherapy.
  - if you use any medicine that stops your bone marrow from working properly
  - if you suffer from bone marrow disease or have ever suffered from bone marrow disease
  - if you suffer from uncontrolled epilepsy (seizures or fits)
  - if you are currently taking carbamazepine (for fits)
  - have an acute mental illness caused by alcohol or drugs (e.g. narcotics)
  - suffer from glaucoma (increased pressure in the eyes)

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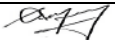
- suffer from circulatory collapse which may occur as a result of severe shock and/or suffer from reduced consciousness and severe drowsiness
- suffer from any severe kidney disease
- suffer from myocarditis (an inflammation of the heart muscle) or from any other severe heart disease
- have symptoms of active liver disease such as jaundice (yellow colouring of the skin and eyes, feeling sick and loss of appetite)
- suffer from any other severe liver disease
- suffer from paralytic ileus (your bowel does not work properly and you have severe constipation)
- CLOZAPINE OETHMAAN should not be given to children under 16 years of age
- if you have or ever had blood clots or a family history of blood clots.

### Warnings and precautions

**The safety measures mentioned in this section are very important. You must comply with them to minimise the risk of serious life-threatening side effects.**

Tell your doctor or healthcare provider before you take CLOZAPINE OETHMAAN if you have or ever had:

- blood clots or family history of blood clots, as medicines like these have been associated with formation of blood clots
- glaucoma (increased pressure in the eye)

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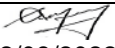
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- diabetes. Elevated (sometimes considerably) blood sugar levels have occurred in patients with or without diabetes mellitus in their medical history (see section 4)
- prostate problems or difficulty in urinating
- any heart, kidney or liver disease
- chronic constipation or if you are taking medicines which cause constipation (such as anticholinergics)
- controlled epilepsy
- large intestine diseases
- abdominal surgery
- a heart disease or family history of abnormal conduction in the heart called “prolongation of the QT interval”
- a risk for having a stroke, for example if you have high blood pressure, cardiovascular problems or blood vessel problems in the brain.

**Medical check-ups and blood tests**

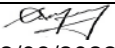
- Before you start taking CLOZAPINE OETHMAAN, your doctor will ask about your medical history and do a blood test to ensure that your white blood cell count is normal. It is important to find this out, as your body needs white blood cells to fight infections.

**Make sure that you have regular blood tests before you start treatment, during treatment and after you stop treatment with CLOZAPINE OETHMAAN.**

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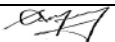
- Your doctor will tell you exactly when and where to have the tests. CLOZAPINE OETHMAAN may only be taken if you have a normal blood cell count.
- CLOZAPINE OETHMAAN can cause a serious decrease in the number of white cells in your blood (agranulocytosis). Only regular blood tests can tell the doctor if you are at risk of developing agranulocytosis.
- During the first 18 weeks of treatment, tests are needed once a week. Between weeks 18 and 52, tests are needed at least every 2 weeks. Afterwards, tests are needed at least once a month.
- If there is a decrease in the number of white blood cells, you will have to stop CLOZAPINE OETHMAAN treatment immediately. Your white blood cells should then return to normal.
- You will need to have blood tests for another 4 weeks after the end of CLOZAPINE OETHMAAN treatment.
- Your doctor will also do a physical examination before starting treatment. Your doctor may do an electrocardiogram (ECG) to check your heart, but only if this is necessary for you, or if you have any special concerns.
- If you have a liver disorder you will have regular liver function tests as long as you continue to take CLOZAPINE OETHMAAN.
- If you suffer from high levels of sugar in the blood (diabetes) your doctor may regularly check your level of sugar in the blood.
- CLOZAPINE OETHMAAN may cause alteration in blood lipids. CLOZAPINE OETHMAAN may cause weight gain. Your doctor may monitor your weight and blood lipid level.

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**Tell your doctor immediately before taking the next CLOZAPINE OETHMAAN tablet if you:**

- get signs of a **cold, fever, flu-like symptoms, sore throat or any other infection**. You will have to have an urgent blood test to check if your symptoms are related to your medicine.
- have a sudden **rapid increase in body temperature, rigid muscles** which may lead to unconsciousness (neuroleptic malignant syndrome) as you may be experiencing a serious side effect which requires immediate treatment.
- have a **fast and irregular heartbeat**, even when you are at rest, **palpitations, breathing problems, chest pain or unexplained tiredness**. Your doctor will need to check your heart and if necessary, refer you to a cardiologist immediately.
- Experience **constipation, abdominal pain, abdominal tenderness, fever, bloating** and/or **bloody diarrhoea**. Your doctor will need to examine you.
- Experience **nausea (feeling sick), vomiting (being sick) and/or loss of appetite**. Your doctor will need to check your liver.
- have to undergo surgery or if for some reason you are unable to walk around for a long time, discuss with your doctor the fact that you are taking CLOZAPINE OETHMAAN. You may be at risk of thrombosis (blood clotting within a vein).
- If you already feel that CLOZAPINE OETHMAAN makes you light-headed, dizzy or faint, be careful when getting up from a sitting or lying position, as this may increase the possibility of falling.

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### Older people (aged 60 years and over)

- Older people (aged 60 years and over) may be more likely to have the following side effects during treatment with CLOZAPINE OETHMAAN: faintness or light-headedness after changing position, dizziness, fast heartbeat, difficulty in passing urine and constipation.

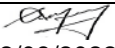
### Other medicines and CLOZAPINE OETHMAAN

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

**Do not take CLOZAPINE OETHMAAN together with medicines that stop the bone marrow from working properly and/or decrease the number of blood cells produced by the body, such as:**

- carbamazepine, a medicine used in epilepsy.
- certain antibiotics: chloramphenicol, sulphonamides such as co-trimoxazole.
- certain painkillers: pyrazolone analgesics such as phenylbutazone.
- penicillamine, a medicine used to treat rheumatic joint inflammation.
- cytotoxic agents, medicines used in chemotherapy.
- long-acting depot injections of antipsychotic medicines.

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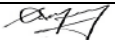
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These medicines increase your risk of developing agranulocytosis (lack of white blood cells).

**Taking CLOZAPINE OETHMAAN at the same time as another medicine may affect how well CLOZAPINE OETHMAAN and/or the other medicine works.**

**Tell your doctor if you plan to take, if you are taking (even if the course of treatment is about to end) or if you have recently had to stop taking any of the following medicines:**

- medicines used to treat depression such as lithium, fluvoxamine, tricyclic antidepressants, MAO inhibitors, citalopram, paroxetine, fluoxetine, and sertraline
- other antipsychotic medicines used to treat mental illnesses
- benzodiazepines and other medicines used to treat anxiety or sleep disturbances
- narcotics and other medicines which can affect your breathing
- medicines used to control epilepsy such as phenytoin and valproic acid
- medicines used to treat high or low blood pressure such as adrenaline and noradrenaline
- warfarin, a medicine used to prevent blood clots
- antihistamines, medicines used for colds or allergies such as hay fever
- anticholinergic medicines, which are used to relieve stomach cramps, spasms and travel sickness
- medicines used to treat Parkinson's disease
- digoxin, a medicine used to treat heart problems
- medicines used to treat a fast or irregular heart beat
- some medicines used to treat stomach ulcers, such as omeprazole or cimetidine
- some antibiotic medicines, such as erythromycin and rifampicin

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- some medicines used to treat fungal infections (such as ketoconazole) or viral infections (such as protease inhibitors, used to treat HIV infections)
- atropine, a medicine which may be used in some eye drops or cough and cold preparations
- adrenaline, a medicine used in emergency situations
- hormonal contraceptives (birth control medicines)

### **CLOZAPINE OETHMAAN with food and drink and alcohol**

CLOZAPINE OETHMAAN may be taken with or without food. Do not drink alcohol during treatment with CLOZAPINE OETHMAAN.

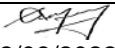
Tell your doctor if you smoke and how often you have drinks containing caffeine (coffee, tea, cola). Sudden changes in your smoking habits or caffeine drinking habits can also change the effects of CLOZAPINE OETHMAAN.

### **Pregnancy and 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.

### **Pregnancy**

The safe use of CLOZAPINE OETHMAAN in pregnant women has not been established.

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The following symptoms may occur in newborn babies, of mothers that have used CLOZAPINE OETHMAAN in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

### **Breast-feeding**

Do not breast-feed during treatment with CLOZAPINE OETHMAAN. Clozapine, the active substance of CLOZAPINE OETHMAAN may pass into your milk and affect your baby.

### **Women of childbearing potential**

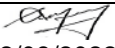
Some women taking some medicines to treat mental illnesses have irregular or no periods. If you have been affected in this way, your periods might return when your medicine is changed to CLOZAPINE OETHMAAN. This means you should use effective contraception.

### **Driving and using machines**

CLOZAPINE OETHMAAN might cause tiredness, drowsiness and seizures, especially at the beginning of treatment.

You should not drive or operate machines while you have these symptoms.

### **CLOZAPINE OETHMAAN contains:**

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CLOZAPINE OETHMAAN contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CLOZAPINE OETHMAAN.

### 3. How to take CLOZAPINE OETHMAAN

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

Always take CLOZAPINE OETHMAAN exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of CLOZAPINE OETHMAAN is too strong or too weak talk to your doctor or pharmacist.

Your doctor will tell you exactly how much medicine to take and when to take it.

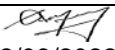
Your doctor will decide on the correct dose depending on your condition and if you are using any other medicines.

The recommended starting dose is 12,5 mg (half a tablet of CLOZAPINE 25 mg OETHMAAN) once or twice a day. Your doctor may need to gradually increase your medication to determine the proper dose for you. This may take 2 to 3 weeks to achieve.

Swallow each tablet with a glass of water.

Do not crush or chew the tablets.

#### If you take more CLOZAPINE OETHMAAN than you should

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

Symptoms of an overdose may include dry mouth, dry skin, drowsiness, tiredness, lack of energy, unconsciousness, coma, confusion, hallucinations, agitation, incoherent speech, stiff limbs, trembling hands, seizures (fits), increased production of saliva, widening of the black part of the eye, blurred vision, low blood pressure, collapse, fast or irregular heartbeat, shallow or difficult breathing.

#### **If you forget to take CLOZAPINE OETHMAAN**

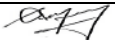
It is important to take your CLOZAPINE OETHMAAN regularly at the same time each day. If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, just carry on with the next dose as normal.

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

Contact your doctor as soon as possible if you have not taken any CLOZAPINE OETHMAAN for more than 48 hours.

#### **If you stop taking CLOZAPINE OETHMAAN**

Do not stop taking CLOZAPINE OETHMAAN without asking your doctor, because you might get withdrawal reactions. These reactions include sweating, headache, nausea (feeling sick), vomiting (being sick) and diarrhoea. **If you have any of the above signs, tell your doctor**

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**straight away. These signs may be followed by more serious side effects unless you are treated immediately.** Your original symptoms might come back. A gradual reduction in dose in steps of 12,5 mg over one to two weeks is recommended, if you have to stop treatment. Your doctor will advise you on how to reduce your daily dose. If you have to stop CLOZAPINE OETHMAAN treatment suddenly, you will have to be checked by your doctor.

If your doctor decides to re-start the treatment with CLOZAPINE OETHMAAN and your last dose of CLOZAPINE OETHMAAN was over two days ago, this will be with the starting dose of 12,5 mg.

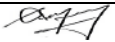
#### 4. Possible side effects:

CLOZAPINE OETHMAAN can have side effects.

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

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

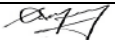
- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

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- crushing chest pain, sensation of chest tightness, pressure or squeezing (chest pain may radiate to the left arm, jaw, neck and upper abdomen), shortness of breath, sweating, weakness, light headedness, nausea, vomiting and palpitations (symptoms of heart attack) which may lead to death. You should seek emergency medical treatment immediately.
- chest pressure, heaviness, tightness, squeezing, burning or choking sensation (signs of insufficient blood flow and oxygen to the heart muscle) which may lead to death. Your doctor will need to check your heart.
- burning upper abdominal pain, particularly between meals, early in the morning, or after drinking acidic drinks; tarry, black, or bloody stools; bloating, heartburn, nausea or vomiting, early feeling of fullness (intestinal ulceration of stomach and/or gut) - which may lead to death.
- severe abdominal pain intensified by movement, nausea, vomiting including vomiting blood (or liquid with what looks like coffee grounds); abdomen becomes rigid with (rebound) tenderness spreading from point of perforation across the abdomen; fever and/or chills (intestinal perforation of stomach and/or gut or ruptured bowel) which may lead to death.
- constipation, abdominal pain, abdominal tenderness, fever, bloating, bloody diarrhoea. This may indicate possible megacolon (enlargement of the intestines) or intestinal infarction/ischaemia/necrosis which may lead to death. Your doctor will need to examine you.

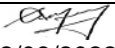
These are all very serious side effects. If you have them, you may have had a serious reaction to CLOZAPINE OETHMAAN. You may need urgent medical attention or hospitalisation.

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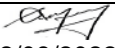
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- proven or strongly suspected infection along with fever or low body temperature, abnormally rapid breathing, rapid heart rate, change in responsiveness and awareness, drop in blood pressure (sepsis).
- signs of a cold, fever, flu-like symptoms, sore throat or any other infection. You will have to have an urgent blood test to check if your symptoms are related to your medicine.
- spontaneous bleeding or bruising, which might be signs of a decrease in numbers of blood platelets.
- a combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- nausea or vomiting, abdominal pain, excessive thirst, excessive urination, disorientation or confusion (symptoms due to uncontrolled blood sugar).
- a sudden rapid increase in body temperature, rigid muscles which may lead to unconsciousness (neuroleptic malignant syndrome) as you may be experiencing a serious side effect which requires immediate treatment.
- profuse sweating, headache, nausea, vomiting and diarrhoea (symptoms of cholinergic syndrome).

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- fast and irregular heartbeat, even when you are at rest, palpitations, breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary refer you to a cardiologist immediately.
- rapid and irregular heartbeats (atrial fibrillation). There may be occasional heart palpitations, fainting, shortness of breath, or chest discomfort.
- intermittent “thumping”, “pounding” or “fluttering” sensation in the chest (palpitations).
- light-headedness, dizziness or fainting, when getting up from a sitting or lying position as it may increase the possibility of falling.
- sudden fainting or loss of consciousness with muscle weakness (syncope).
- symptoms of low blood pressure such as light-headedness, dizziness, fainting, blurred vision, unusual fatigue, cold and clammy skin or nausea.
- signs of blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- signs of a respiratory tract infection or pneumonia such as fever, coughing, difficulty breathing, wheezing.
- sharp chest pain with shortness of breath and with or without coughing or fever.
- severe constipation. Your doctor will have to treat this in order to avoid further complications.
- abdominal pain, cramping, swollen abdomen, vomiting, constipation and failure to pass gas which may be signs and symptoms of bowel obstruction.

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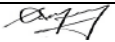
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- nausea (feeling sick), vomiting (being sick), loss of appetite swollen abdomen, abdominal pain, yellowing of the skin, severe weakness and malaise. Your doctor will need to check your liver.
- if you develop jaundice (yellowing of the skin or whites of the eyes) and darkening of urine (symptoms of liver inflammation or liver failure).
- severe upper abdominal pain, extending to the back accompanied by nausea and vomiting due to inflammation of the pancreas.
- nausea, vomiting, fatigue, weight loss which may be symptoms of inflammation of the kidney.
- severely decreased urine output (sign of kidney failure).
- increased or new muscle weakness, muscle spasms, muscle pain. This may indicate a possible muscle disorder (rhabdomyolysis). Your doctor will need to examine you.
- if you are a man, persistent painful erection of the penis. This is called priapism. If you have an erection which lasts more than 4 hours, immediate medical treatment may be needed in order to avoid further complications.
- sharp chest, joint or abdominal pain with or without shortness of breath or fever (polyserositis).

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

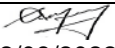
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- High level of white blood cells (leukocytosis)
- high level of a specific type of white blood cell (eosinophilia)
- weight gain
- speech disorders (e.g. slurred speech)
- seizures, drowsiness, dizziness, headache, trembling, stiffness, inability to stay still, jerks, abnormal movements, inability to initiate movement
- blurred vision
- fast heartbeat, changes in ECG heart readings
- high blood pressure, faintness or light-headedness after changing position, fainting
- constipation, increased production of saliva, nausea (feeling sick), vomiting (being sick), loss of appetite, dry mouth
- minor abnormalities in liver function tests
- loss of bladder control, difficulty in passing urine
- tiredness, fever, increased sweating, raised body temperature

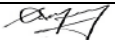
#### **Less frequent side effects**

- Lack of white blood cells (agranulocytosis)
- a decrease in the number of white blood cells
- reduction in number of red blood cells (anaemia)
- increase in numbers of blood platelets with possible clotting in the blood vessels
- sudden, uncontrollable increase in blood pressure (pseudophaeochromocytoma)
- complications due to uncontrolled blood sugar (e.g. coma or ketoacidosis), obesity
- restlessness, agitation, speech disorder (e.g. stuttering)

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- confusion, delirium, uncontrollable movements of mouth/tongue and limbs, obsessive thoughts and compulsive repetitive behaviours (obsessive compulsive symptoms), uncontrolled bending of the body to one side (pleurothotonus), changes in brain waves readings (electroencephalogram/EEG, restless legs syndrome (irresistible urge to move your legs or arms, usually accompanied by uncomfortable sensations during periods of rest, especially in the evening or at night and temporarily relieved by movement)
- inflammation of the heart muscle (myocarditis) or the membrane surrounding the heart muscle (pericarditis), fluid collection around the heart (pericardial effusion), stopped heartbeat (cardiac arrest)
- low blood pressure
- difficulty in swallowing (which may cause inhalation of food), interruption in breathing with or without snoring during sleep, stuffy nose
- swelling in front of the ear (enlargement of salivary glands), inflammation of the colon resulting in diarrhoea, abdominal pain, heartburn, ingestion
- liver disorders including fatty liver disease, death of liver cells, liver toxicity/injury, liver disorders that involve replacement of normal liver tissue with scar tissue leading to loss of liver function, including those liver events leading to life-threatening consequences such as liver failure (which may lead to death), liver injury (injury of liver cells, bile duct in the liver, or both) and liver transplant
- skin reactions, change in skin colour
- muscle weakness, muscle spasms, muscle pain, “butterfly” facial rash, joint pain, muscle pain, fever and fatigue (lupus erythematosus)

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- nocturnal bedwetting
- ejaculatory disorder if you are a male, in which semen enters the bladder instead of ejaculating through the penis (dry orgasm or retrograde ejaculation)
- sudden unexplained death
- laboratory test may show the following:
  - a. blood test results for liver function or fat levels differing from normal
  - b. weight gain
  - c. raised levels of an enzyme called creatinine phosphokinase in the blood.

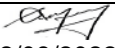
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CLOZAPINE OETHMAAN.

### 5. How to store CLOZAPINE OETHMAAN

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

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Store in a dry place below 25 °C.

Protect from light and moisture.

Store in the original package/container.

Keep the blister in the carton until required for use.

Do not store in a bathroom.

Do not use CLOZAPINE OETHMAAN after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

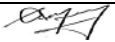
## 6. Contents of the pack and other information

### What CLOZAPINE OETHMAAN contains

The active substance in each tablet is clozapine 25 mg or 50 mg or 100 mg.

The other ingredients are: Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polyvinylpyrrolidone K25, sodium lauryl sulphate, sodium starch glycolate.

### What CLOZAPINE OETHMAAN looks like and contents of the pack

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**CLOZAPINE 25 OETHMAAN:**

Round, light yellow tablets with break notch and embossment.

Diameter: 5,8 to 6,2 mm. Height: 2,7 to 3,1 mm.

**CLOZAPINE 50 OETHMAAN:**

Round, light yellow tablets with break notch and embossment.

Diameter: 7,8 to 8,2 mm. Height: 3,5 to 4,0 mm.

**CLOZAPINE 100 OETHMAAN:**

Round, light yellow tablets with break notch and embossment.

Diameter: 8,8 to 10,2 mm. Height: 4,3 to 4,7 mm.

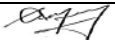
**CLOZAPINE 25 OETHMAAN, CLOZAPINE 50 OETHMAAN and CLOZAPINE 100 OETHMAAN:**

White opaque PVC / Aluminium blister strips containing 10 tablets each.

10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton.

**Holder of Certificate of Registration**

Oethmaan Biosims (Pty) Ltd

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207A Sherwood House

Greenacres Office Park

c/o Victory and Rustenberg Roads

Victory Park

Johannesburg

2195

**This leaflet was last revised in**

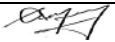
02 August 2022

**Registration number**

CLOZAPINE 25 OETHMAAN: 37/2.6.5/0188

CLOZAPINE 50 OETHMAAN: 37/2.6.5/0189

CLOZAPINE 100 OETHMAAN: 37/2.6.5/0190

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