Package Leaflet: Information for the patient

Clozaril 200 mg tablets
clozapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Clozaril is and what it is used for

Clozaril contains the active substance clozapine which belongs to a group of medicines called antipsychotics (medicines that are used to treat specific mental disorders such as psychosis).

Clozaril is used to treat adults with schizophrenia in whom other medicines have not worked. Schizophrenia is a mental illness which affects how you think, feel and behave. You should only use this medicine if you have already tried at least two other antipsychotic medicines, including one of the newer atypical antipsychotics, to treat schizophrenia, and these medicines did not work, or caused severe side effects that cannot be treated.

Clozaril is also used to treat adults with severe disturbances in the thoughts, emotions and behaviour of people with Parkinson's disease in whom other medicines have not worked.

2. What you need to know before you take Clozaril

Do not take Clozaril if you:
- are allergic to clozapine or any of the other ingredients of this medicine (listed in section 6).
- are not able to have regular blood tests.
- have ever been told you have a low white blood cell count (e.g. leucopenia 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.
- had to stop using Clozaril previously because of severe side effects (e.g. agranulocytosis or heart problems).
- are being or have been treated with long-acting depot injections of antipsychotics.
- suffer from bone marrow disease or have ever suffered from bone marrow disease.
- suffer from uncontrolled epilepsy (seizures or fits).
- have an acute mental illness caused by alcohol or drugs (e.g. narcotics).
- suffer from reduced consciousness and severe drowsiness.
- suffer from circulatory collapse which may occur as a result of severe shock.
- suffer from any severe kidney disease.
- suffer from myocarditis (an inflammation of the heart muscle).

- suffer 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).
- use any medicine that stops your bone marrow from working properly.
- use any medicine that reduces the number of white cells in your blood.

If any of the above applies to you, tell your doctor and do not take Clozaril.

Clozaril must not be given to anyone who is unconscious or in a coma.

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.

Before you start treatment with Clozaril, tell your doctor 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).
- diabetes. Elevated (sometimes considerably) blood sugar levels, has 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).
- galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.
- 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.
- developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Clozaril.

This medicine can cause serious skin reactions. Stop using clozapine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions.

Tell your doctor immediately before taking the next Clozaril 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 **fast and irregular heart beat**, 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 **nausea (feeling sick), vomiting (being sick)** and/or **loss of appetite**. Your doctor will need to check your liver.
- have **severe constipation**. Your doctor will have to treat this in order to avoid further complications.
- experience **constipation**, **abdominal pain**, **abdominal tenderness**, **fever**, **bloating** and/or **bloody diarrhoea**. Your doctor will need to examine you.
- develop signs and symptoms of appendicitis; these may include intense and worsening abdominal pain that begins near the navel and moves to the lower right side, made worse by movement, coughing or pressing the area. Other signs can include constipation, abdominal swelling malaise, mild fever, vomiting, loss of appetite or diarrhea. You will need an urgent medical examination by your doctor.

Medical check-ups and blood tests
Before you start taking Clozaril, your doctor will ask about your medical history and do a blood test to ensure that your white blood cells 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 Clozaril.

- Your doctor will tell you exactly when and where to have the tests. Clozaril may only be taken if you have a normal blood count.
- Clozaril 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 (see section 4).
- During the first 18 weeks of treatment, blood tests are needed once a week. Afterwards, tests are needed at least once a month for the following 34 weeks.
- After 12 months of treatment, blood tests must be performed every 12 weeks for a year, and then yearly, if a decrease in the number of white cells in your blood is not detected.
- If there is a decrease in the number of white blood cells, you will have to stop Clozaril 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 Clozaril treatment in case of complete discontinuation caused by haematological reasons (i.e. agranulocytosis) or in case of duration of monitoring < 2 years and/or in presence of history of neutropenia that had not led to treatment interruption.

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 Clozaril.
If you suffer from high levels of sugar in the blood (diabetes) your doctor may regularly check your level of sugar in the blood.
Clozaril may cause alteration in blood lipids. Clozaril may cause weight gain. Your doctor may monitor your weight and blood lipid level.

If you already suffer from feeling or if Clozaril makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position as these may increase the possibility of falling.

If you 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 Clozaril. You may be at risk of thrombosis (blood clotting within a vein).

Children and adolescents under 16 years
If you are under 16 years of age you should not use Clozaril as there is not enough information on its use in that age group.

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 Clozaril: faintness or light-headedness after changing position, dizziness, fast heart beat, difficulty in passing urine, and constipation.

Tell your doctor or pharmacist if you suffer from a condition called dementia.

Other medicines and Clozaril
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription or herbal therapies. You might need to take different amounts of your medicines or to take different medicines.

Do not take Clozaril 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.
- cytoxic agents, medicines used in chemotherapy.
- long-acting depot injections of antipsychotic medicines.

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

Taking Clozaril at the same time as another medicine may affect how well Clozaril 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 such as perazine.
- 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.
- 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 tablets).

This list is not complete. Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking Clozaril. They will also know if the medicines you are taking belong to the listed groups. Speak to them.

Clozaril with food and drink
Do not drink alcohol during treatment with Clozaril.

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 Clozaril.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the benefits and possible risks of using this medicine during pregnancy. Tell your doctor immediately if you become pregnant during treatment with Clozaril.
The following symptoms may occur in newborn babies, of mothers that have used Clozaril 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.

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 Clozaril. This means you should use effective contraception.

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

Driving and using machines
Clozaril might cause tiredness, drowsiness and seizures, especially at the beginning of treatment. You should not drive or operate machines while you have these symptoms.

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

3. How to take Clozaril

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

In order to minimise the risk of low blood pressure, seizures and drowsiness it is necessary that your doctor increases your dose gradually.
It is important that you do not change your dose or stop taking Clozaril without asking your doctor first. Continue taking the tablets for as long as your doctor tells you. If you are 60 years or older, your doctor may start you on a lower dose and increase it more gradually because you might be more likely to develop some unwanted side effects (see section 2 “Before you take Clozaril”).

If the dose you are prescribed cannot be achieved with this strength tablet, other strengths of this medicinal product are available to achieve the dose.

Treatment of schizophrenia
The usual starting dose is 12.5 mg (one half of a 25 mg tablet) once or twice on the first day followed by 25 mg once or twice on the second day. Swallow the tablet with water. If tolerated well, your doctor will then gradually increase the dose in steps of 25-50 mg over the next 2-3 weeks until a dose up to 300 mg per day is reached. Thereafter, if necessary, the daily dose may be increased in steps of 50 to 100 mg half-weekly or, preferably, at weekly intervals.

The effective daily dose is usually between 200 mg and 450 mg, divided into several single doses per day. Some people might need more. A daily dose of up to 900 mg is allowed. Increased side effects (in particular seizures) are possible at daily doses over 450 mg. Always take the lowest effective dose for you. Most people take part of their dose in the morning and part in the evening. Your doctor will tell you exactly how to divide your daily dose. If your daily dose is only 200 mg, then you can take this as a single dose in the evening. Once you have been taking Clozaril with successful results for some time, your doctor may try you on a lower dose. You will need to take Clozaril for at least 6 months.

Treatment of severe thought disturbances in patients with Parkinson’s disease
For dosing in Psychotic disorders in Parkinson’s disease more appropriate pharmaceutical dosage forms are available.
The usual starting dose is 12.5 mg (one half of a 25 mg tablet) in the evening. Swallow the tablet with water. Your doctor will then gradually increase the dose in steps of 12.5 mg, not faster than two steps a week, up to a maximum dose of 50 mg by the end of the second week. Increases in the dosage should be stopped or postponed if you feel faint, light-headed or confused. In order to avoid such symptoms your blood pressure will be measured during the first weeks of treatment.

The effective daily dose is usually between 25 mg and 37.5 mg, taken as one dose in the evening.
Doses of 50 mg per day should only be exceeded exeptionally.The maximum daily dose is 100 mg. Always take the lowest effective dose for you.

Method of administration
Clozaril is for oral use.
The tablet can be divided into equal doses.

If you take more Clozaril than you should
If you think that you may have taken too many tablets, or if anyone else takes any of your tablets, contact a doctor immediately or call for emergency medical help.
The symptoms of overdose are:
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 heart beat, shallow or difficult breathing.

If you forget to take Clozaril
If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, leave out the forgotten tablets and take the next dose at the right time. Do not take a double dose to make up for a forgotten dose. Contact your doctor as soon as possible if you have not taken any Clozaril for more than 48 hours.

If you stop taking Clozaril
Do not stop taking Clozaril 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 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 Clozaril treatment suddenly, you will have to be checked by your doctor.
If your doctor decides to re-start the treatment with Clozaril and your last dose of Clozaril was over two days ago, this will be with the starting dose of 12.5 mg.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Clozaril can cause side effects, although not everybody gets them.

Some side effects can be serious and need immediate medical attention:
Tell your doctor immediately before taking the next Clozaril tablet if you experience any of the following:

- **severe constipation**. Your doctor will have to treat this in order to avoid further complications.
- 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.
- abdominal pain, cramping, swollen abdomen, vomiting, constipation and failure to pass gas which may be signs and symptoms of bowel obstruction.
- 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
- low number of white blood cells as shown in a blood test (agranulocytosis).
- 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.

- 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 respiratory tract infection or pneumonia such as fever, coughing, difficulty breathing, wheezing.
- seizures.
- **fast and irregular heart beat**, 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.
- 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.
- disorder of the heart muscle (cardiomyopathy), stopped heart beat (cardiac arrest).
- irregular heart beat, inflammation of the heart muscle (myocarditis) or the membrane surrounding the heart muscle (pericarditis), fluid collection around the heart (pericardial effusion).
- 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.
- intermittent "thumping," "pounding," or "fluttering" sensation in the chest (palpitations).
- rapid and irregular heartbeats (atrial fibrillation). There may be occasional heart palpitations, fainting, shortness of breath, or chest discomfort. Your doctor will need to check your heart.
- loss of appetite, swollen abdomen, abdominal pain, yellowing of the skin, severe weakness and malaise. This may indicate possible 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 fulminant liver necrosis, liver failure (which may lead to death), liver injury (injury of liver cells, bile duct in the liver, or both) and liver transplant.
- 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.
- inflammation of the appendix (appendicitis).

If any of the above apply to you, please tell your doctor immediately before taking the next Clozaril tablet.

Other side effects:

Very common (may affect more than 1 in 10 people):
Drowsiness, dizziness, increased production of saliva.

Common (may affect up to 1 in 10 people):
High level of white blood cells (leukocytosis), high level of a specific type of white blood cell (eosinophilia), weight gain, blurred vision, headache, trembling, stiffness, restlessness, convulsions, jerks, abnormal movements, inability to initiate movement, inability to remain motionless, changes in ECG heart machine, high blood pressure, faintness or light-headedness after changing position, dry mouth, minor abnormalities in liver function tests, loss of bladder control, difficulty in passing urine, tiredness increased sweating, raised body temperature, speech disorders (e.g. slurred speech), sudden fainting or sudden loss of consciousness with muscle weakness (syncope).

Uncommon (may affect up to 1 in 100 people):
Speech disorders (e.g. stuttering), light-headedness, dizziness or fainting, when getting up from a sitting or lying position as it may increase the possibility of falling.

Rare (may affect up to 1 in 1,000 people):
Low level of red blood cells (anaemia), restlessness, agitation, confusion, delirium, high level of sugar in the blood, diabetes mellitus, blood clot in the lungs (thromboembolism), inflammation of the liver (hepatitis), liver disease causing yellowing of the skin/dark urine/itching, raised levels of an enzyme called creatinine phosphokinase in the blood, severe, burning, upper abdominal pain extending to the back accompanied by nausea and vomiting due to inflammation of the pancreas, fainting and muscle weakness due to a significant

drop in blood pressure (circulatory collapse), difficulty in swallowing (which may cause inhalation of food), nausea (feeling sick), vomiting (being sick) and/or loss of appetite. Your doctor will need to check your liver signs of becoming obese or increasing obesity, interruption in breathing with or without snoring during sleep.

Very rare (may affect up to 1 in 10,000 people):
Increase in numbers of blood platelets with possible clotting in the blood vessels, uncontrollable movements of mouth/tongue and limbs, obsessive thoughts and compulsive repetitive behaviours (obsessive compulsive symptoms), skin reactions, swelling in front of the ear (enlargement of saliva glands), difficulty in breathing, very high levels of triglycerides or cholesterol in the blood, sudden unexplained death, persistent painful erection of the penis, if you are a man. 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, spontaneous bleeding or bruising, which might be signs of a decrease in numbers of blood platelets, symptoms due to uncontrolled blood sugar (such as nausea or vomiting, abdominal pain, excessive thirst, excessive urination, disorientation or confusion), nausea, vomiting, fatigue, weight loss which may be symptoms of inflammation of the kidney.

Not known (frequency cannot be estimated from the available data)
Changes in brain waves machine (electroencephalogram/EEG), diarrhoea, stomach discomfort, heartburn, stomach discomfort after a meal, muscle weakness, muscle spasms, muscle pain, stuffy nose, nocturnal bedwetting, sudden, uncontrollable increase in blood pressure (pseudophaeochromocytoma), uncontrolled bending of the body to one side (pleurothotonus), ejaculatory disorder if you are a male, in which semen enters the bladder instead of ejaculating through the penis (dry orgasm or retrograde ejaculation), rash, purplish-red spots, fever or itching due to inflammation of blood vessel, inflammation of the colon resulting in diarrhoea, abdominal pain, fever, change in skin colour, “butterfly” facial rash, joint pain, muscle pain, fever and fatigue (lupus erythematous), 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), 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, profuse sweating, headache, nausea, vomiting and diarrhoea (symptoms of cholinergic syndrome), severely decreased urine output (sign of kidney failure), an allergic reaction (swelling mainly of the face, mouth and throat, as well as, the tongue, which may be itchy or painful), sharp chest pain with shortness of breath and with or without coughing, increased or new muscle weakness, muscle spasms, muscle pain. This may indicate possible a muscle disorder (rhabdomyolysis). Your doctor will need to examine you, sharp chest or abdominal pain with shortness of breath and with or without coughing or fever, extremely intense and serious skin reactions, such as drug rash with eosinophilia and systemic symptoms (DRESS syndrome), have been reported during use of X. The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, oedema and fever and flulike symptoms may occur. Symptoms of DRESS syndrome usually appear approximately 2–6 weeks (possibly up to 8 weeks) after treatment begins.

Blood cancer (haematological malignancy)
A small increased risk of developing blood cancer has been observed in patients taking clozapine, especially in cases of longer treatment.

Symptoms could include
- unexplained fever
- swollen glands,
- persistent infections during the treatment
- weight loss
- extreme tiredness
- redness
- night sweats
- easy bruising or bleeding

In elderly people with dementia, a small increase in the number of people dying has been reported for patients taking antipsychotics compared with those not taking antipsychotics.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Clozaril

- Keep this medicine out of the sight and reach of children.
- Do not use Clozaril after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clozaril contains
- The active substance is clozapine. Each tablet contains 200 mg clozapine.
- The other ingredients are magnesium stearate, anhydrous colloidal silica, povidone K30, talc, maize starch, lactose monohydrate.

What Clozaril looks like and contents of the pack

A light yellow, round, biconvex tablet, debossed with press type cross breakline on one side of the tablet and V C 7 cross breakline on the other side.
Diameter: Approximately 13 mm

Clozaril tablets are available in PVC/PE/PVdC – Aluminium blisters containing 20, 30, 40,50, or 100 tablets, or PVC/PE/PVdC - Aluminium perforated unit-dose blisters containing 20 x 1, 30 x 1, 40 x 1, 50 x 1, 100 x 1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatris Healthcare Limited,
Damastown Industrial Park,
Mulhuddart,
Dublin 15,
DUBLIN,
Ireland

Manufacturer

Madaus GmbH
Luetticher Strasse 5,
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Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Leponex 200 mg tabletten
Croatia	Leponex 200 mg tablete

Czech Republic	Leponex 200 mg tablety
Finland	Leponex
Germany	Leponex 200 mg Tabletten
Greece	Leponex
Hungary	Leponex 200mg tabletta
Ireland	Clozaril 200 mg tablets
Luxembourg	Leponex 200 mg comprimés
Spain	Leponex 200 mg comprimidos
Slovenia	Leponex 200 mg tablete

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