

CLOZARIL ODT®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before taking this medicine.

1. Why am I taking CLOZARIL ODT?

CLOZARIL ODT contains the active ingredient clozapine. CLOZARIL ODT is used to treat schizophrenia, which is a mental illness with disturbances in thinking, feelings and behaviour.

For more information, see Section [1. Why am I taking CLOZARIL ODT?](#) in the full CMI.

2. What should I know before I take CLOZARIL ODT?

Do not take if you have ever had an allergic reaction to clozapine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take CLOZARIL ODT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLOZARIL ODT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take CLOZARIL ODT?

The usual starting dose is 12.5 mg once or twice daily on the first day. The dose is usually increased to 25 mg once or twice daily on the second day. After that, the dose can be slowly increased until the desired effect is achieved. More instructions can be found in Section [4. How do I take CLOZARIL ODT?](#) in the full CMI.

5. What should I know while taking CLOZARIL ODT?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking CLOZARIL ODT. - If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CLOZARIL ODT. - You must have strict and regular blood tests while taking CLOZARIL ODT. - Call your doctor straight away if you develop a fever, signs and symptoms of an infection, changes to your bowel movements or become pregnant.
Things you should not do	Do not stop taking this medicine suddenly OR lower the dosage, even if you are feeling better, without checking with your doctor.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how CLOZARIL ODT affects you.
Drinking alcohol	- Tell your doctor if you drink alcohol. - You should not drink alcohol while you are taking CLOZARIL ODT.
Looking after your medicine	- Keep your tablets in a cool dry place where the temperature stays below 25°C and protect from light. - Keep it where children cannot reach it.

For more information, see Section [5. What should I know while taking CLOZARIL ODT?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of the following and they worry you: constipation or fewer bowel movements than normal, abdominal pain, nausea (feeling sick), vomiting, stomach discomfort especially after a meal, diarrhoea, dry mouth.

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following: fever, sore throat, mouth ulcers, "flu-like" symptoms, a fast or irregular heartbeat, sudden signs of allergy, sudden increase in body temperature, muscle stiffness, stomach pain often accompanied by nausea, severe or prolonged constipation.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:**Gastrointestinal hypomotility (reduced gastrointestinal movement) due to clozapine**

CLOZARIL ODT may cause slowing down or blockage of intestine function, resulting in reactions such as constipation; nausea with or without vomiting; tenderness or swelling of the abdomen, or bloating; stomach pains/spasms; leakage of diarrhoea or frequent and forceful bowel movements; bowel urges with no resulting movements; pain or pressure in the rectum and inflammation and bleeding of the bowels from the rectum. These can lead to severe outcomes. Your doctor must monitor bowel function before prescribing and during your therapy with CLOZARIL ODT. It is extremely important to immediately advise your doctor, coordinator, pharmacist or any other healthcare professional, of any changes to your stool/bowel movements.

Myocarditis

CLOZARIL ODT may cause myocarditis (inflammation of heart muscle), which may be fatal, or another heart condition. Your doctor will monitor you during treatment. If required, your doctor may want to refer you to a cardiologist for further tests.

CLOZARIL ODT®

Active ingredient(s): *clozapine*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CLOZARIL ODT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking CLOZARIL ODT.**

Where to find information in this leaflet:

- [1. Why am I taking CLOZARIL ODT?](#)
- [2. What should I know before I take CLOZARIL ODT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take CLOZARIL ODT?](#)
- [5. What should I know while taking CLOZARIL ODT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking CLOZARIL ODT?

CLOZARIL ODT contains the active ingredient clozapine. CLOZARIL ODT belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain which may cause mental illness.

CLOZARIL ODT is used to treat schizophrenia, which is a mental illness with disturbances in thinking, feelings and behaviour.

CLOZARIL ODT is only used to treat patients suffering with schizophrenia when other antipsychotic medicines either have not worked or have caused severe side effects.

Ask your doctor if you have any questions about why CLOZARIL ODT has been prescribed for you.

Your doctor may have prescribed it for another reason.

CLOZARIL ODT is available only with a doctor's prescription. There is no evidence that it is addictive.

CLOZARIL ODT is not recommended for use in children or adolescents under the age of 16, as there is not enough information on its use in that age group.

2. What should I know before I take CLOZARIL ODT?

Warnings**Do not take CLOZARIL ODT if:**

- you are allergic to clozapine, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, mouth and throat, as well as the tongue, which may be itchy or painful; or swelling of other parts of the body; rash, itching or hives on the skin.

If you think that you are allergic to CLOZARIL ODT, ask your doctor for advice before taking this medicine.

Always check the ingredients to make sure you can take this medicine.

- **you have a low white blood cell count or have previously had a low white blood cell count caused by a medicine (except if it was following a treatment for cancer).**

CLOZARIL ODT can cause agranulocytosis (a condition with a reduced number of white blood cells).

These cells are needed to fight infections. If you have a low white blood cell count or have had one in the past, you must not take CLOZARIL ODT.

- **you are unable to have regular blood tests.**

Before starting this medicine and during your therapy, checks will be required to monitor the levels of various components in your blood. Your doctor will tell you when these tests are needed.

- you have any disease of the blood which causes a reduced number of red blood cells or platelets.
- you have symptoms of active liver disease such as jaundice (yellow colour to the skin and eyes, feeling sick, loss of appetite) or any other severe liver disease.
- you have severe kidney disease.

- you have myocarditis (an inflammation of the heart muscle) or any other heart problems.
- you have uncontrolled epilepsy (i.e. you still have some seizures).
- you have paralytic ileus (your bowel does not work properly and you have severe constipation).
- you have severe constipation, obstruction of the bowel, or any other condition which has affected your large bowel.
- you have bone marrow disease.
- you have problems with alcohol or drug abuse.

CLOZARIL ODT must not be given to anyone who is unconscious or in a coma, or who has an acute mental illness caused by alcohol or drugs.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- take any medicines for any other condition.
- **change how much you smoke or drink caffeinated drinks (e.g. coffee).** Sudden changes in your usual smoking or caffeine intake can also change the effects of CLOZARIL ODT.
- **will be in a hot environment or you do a lot of vigorous exercise.** CLOZARIL ODT may make you sweat less, causing your body to overheat.
- have allergies to other medicines or to any other substances such as foods, preservatives or dyes.

Tell your doctor if you have ever had any of the following medical conditions:

- any form of heart disease or a family history of heart disease
- family history of an abnormal conduction in the heart called "prolongation of the QT interval"
- stroke
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma
- tardive dyskinesia, a reaction to some medicines with uncontrolled movements of the tongue, face, mouth or jaw (such as puffing of the cheeks, puckering of the mouth or chewing movements)
- problems with your liver or kidneys
- glaucoma, a condition in which there is usually a build-up of fluid in the eye
- enlargement of the prostate or prostate problems
- epilepsy that is under control (i.e. you no longer have seizures)
- diabetes or a family history of diabetes
- chronic constipation, which needs to be treated before you start taking CLOZARIL ODT. Your doctor must also monitor bowel function while you are on CLOZARIL ODT.

- dementia, a condition in which there is a decline in all areas of mental ability
- phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot break it down properly. CLOZARIL ODT contains aspartame which is a source of phenylalanine.
- any other serious medical condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Experience with CLOZARIL ODT in pregnancy is very limited. If you need to take this medicine during pregnancy, your doctor will discuss with you the benefits and risks of taking it.

Newborn babies of mothers taking antipsychotic drugs during the third trimester of pregnancy may have increased risk of developing stiff limbs, trembling, agitation, muscle stiffness, muscle flaccidity, drowsiness, short and shallow breathing, and feeding disorders following delivery. In some cases these symptoms may be self-limiting, in other cases, babies may require intensive care unit support or hospitalisation.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not breastfeed during CLOZARIL ODT treatment. This medicine may pass into breast milk and may affect your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and CLOZARIL ODT may interfere with each other. These include:

- medicines that decrease the number of blood cells produced by your body
- other antipsychotic medicines used to treat mental illnesses
- medicines used to control depression or mood swings
- benzodiazepines and other medicines used to treat anxiety or to help you sleep
- medicines used to control epilepsy, including phenytoin, carbamazepine and valproic acid
- warfarin, a medicine used to prevent blood clots
- strong pain killers such as morphine
- St John's wort (*Hypericum perforatum*), an ingredient in many medicines that you can buy without a prescription from a pharmacy, health food shop or supermarket
- 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
- medicines used to treat high blood pressure
- digoxin, a medicine used to treat heart problems
- medicines used to treat a fast or irregular heartbeat
- some medicines used to treat stomach ulcers, including cimetidine, omeprazole, pantoprazole and lansoprazole
- some antibiotic medicines, including erythromycin, clarithromycin, azithromycin, ciprofloxacin, norfloxacin and rifampicin
- some medicines used to treat fungal or viral infections
- nicotine in medicines used to help you quit smoking, such as nicotine patches or chewing gum
- atropine, a medicine which may be used in some eye drops or cough and cold preparations
- adrenaline (epinephrine), a drug used in emergency situations
- contraceptive (birth-control) tablets

These medicines may be affected by CLOZARIL ODT or they may affect how well CLOZARIL ODT works. You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CLOZARIL ODT.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CLOZARIL ODT.

4. How do I take CLOZARIL ODT?

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

- The usual starting dose is 12.5 mg once or twice daily on the first day. The dose is usually increased to 25 mg once or twice daily on the second day. After that the dose can be slowly increased until the desired effect is achieved. Usually the total amount of CLOZARIL ODT needed each day will be between 200 mg and 450 mg but some people will need higher doses. Once the maximum benefit is reached, the dose can often be decreased to between 150 mg and 300 mg each day.
- If you have heart, kidney or liver disease, are prone to seizures (fits) or are elderly, your doctor may start you on a lower dose and increase it more gradually to prevent unwanted side effects.
- Follow the instructions provided and take CLOZARIL ODT until your doctor tells you to stop.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

When to take CLOZARIL ODT

- Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.
- The total daily amount of CLOZARIL ODT is usually divided into 2 doses (morning and bedtime). But, if your total dose is 200 mg or less, your doctor may allow you to take the whole amount at once, usually in the evening.

How to take CLOZARIL ODT

- Place the orally disintegrating tablet in the mouth, on the tongue and allow to disintegrate before swallowing with or without water. It should be taken immediately upon removal from the pack. If you require a second tablet, the second tablet should be taken after the first tablet has fully disintegrated.

If you forget to take CLOZARIL ODT

CLOZARIL ODT should be taken regularly at the same time each day.

If you miss your dose and it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you have forgotten to take CLOZARIL ODT for more than 2 days, do not start taking it again before you contact your doctor.

To prevent unwanted side effects, your doctor will probably want you to restart CLOZARIL ODT at a low dose and increase it gradually back to the amount you were taking before.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much CLOZARIL ODT

If you think that you or anyone else have taken too much CLOZARIL ODT, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

The most common symptoms of an overdose include light headedness due to low blood pressure, too much saliva,

difficulty breathing, fast or irregular heartbeat, drowsiness, confusion and unconsciousness.

5. What should I know while taking CLOZARIL ODT?

Things you should do

- **Continue taking CLOZARIL ODT as long as your doctor tells you. If you have questions about how long to take CLOZARIL ODT, talk to your doctor or pharmacist.**
- **You must have strict and regular blood tests while taking CLOZARIL ODT.**

CLOZARIL ODT can cause agranulocytosis. This is a condition where the number of white blood cells in your body is reduced. White blood cells are needed to fight infection.

There is no way of knowing who is at risk of developing agranulocytosis.

Deaths have occurred in severe cases of agranulocytosis. However, with regular blood tests, the problem can be detected early. If CLOZARIL ODT is stopped as soon as possible, the white blood cell numbers should return to normal.

You must have a blood test at least once a week for the first 18 weeks after starting CLOZARIL ODT.

This is the time when the risk of agranulocytosis is greatest. These tests can tell the doctor whether the white blood cell count is dropping.

After 18 weeks, you must have a blood test at least every 4 weeks for as long as you are taking CLOZARIL ODT and for a month after stopping the medicine.

There are some situations where you may need to have blood tests more often (e.g. twice a week). Your doctor will explain this to you.

If the number of white blood cells falls below a critical level, CLOZARIL ODT will be stopped immediately and you must never take CLOZARIL ODT again.

- If you suffer from a high level of sugar in the blood (diabetes) your doctor may regularly check your level of sugar in the blood.
- **Watch for important side effects. If you develop a fast or irregular heartbeat that is present even when you are resting, accompanied by rapid breathing, shortness of breath, swelling of the feet or legs, dizziness or light headedness, or chest pain, contact your doctor immediately as these may cause death.**

These symptoms could be signs of myocarditis, an inflammation of the heart muscle, or another heart condition. Your doctor may want to refer you to a cardiologist for further tests.

- **Make sure you use a contraceptive to prevent pregnancy during treatment with CLOZARIL ODT.**

Some women taking some antipsychotic medications have irregular or no periods. If you are female and you

have been affected in this way, your periods may return when your medication is changed to CLOZARIL ODT.

Call your doctor straight away if you:

- **develop a fever.**
Some patients develop a fever in the first few weeks of taking CLOZARIL ODT. You must be checked carefully to make sure that you do not have agranulocytosis, myocarditis or neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature.
- **develop a sore throat, mouth ulcers, flu-like symptoms or any other sign of a cold or infection.**
Your doctor will check your blood to decide if your symptoms are an early sign of agranulocytosis. Flu-like symptoms may also be a sign of myocarditis.
- **notice any uncontrolled movements of the tongue, face, mouth or jaw, such as puffing of the cheeks, puckering of the mouth or chewing movements.**
These are symptoms of a very rare condition called tardive dyskinesia which may develop in people taking antipsychotic medicines. This condition is more likely to happen during long-term treatment, especially in elderly women. In very rare cases, it may be permanent. However, if detected early, these symptoms are usually reversible.
- **Be mindful of any changes to your gastrointestinal (stomach/intestine) function. CLOZARIL ODT may slow down or block intestinal function causing reactions such as constipation, nausea with or without vomiting, tenderness or swelling of the abdomen, leakage of diarrhoea or frequent and forceful bowel movements, bowel urges with no resulting movements, lower back pain, pain or pressure in the rectum and bleeding from the rectum. These can lead to extremely severe outcomes.**
Your doctor must monitor intestine function before prescribing and during your therapy with CLOZARIL ODT. If you develop any of these symptoms, you must tell your doctor, coordinator, pharmacist or any other healthcare professional of any changes to your bowel movements.
- **become pregnant while taking this medicine.**
Newborn babies of mothers taking antipsychotic drugs during the third trimester of pregnancy may have increased risk of developing stiff limbs, trembling, agitation, muscle stiffness, muscle flaccidity, drowsiness, short and shallow breathing, and feeding disorders following delivery. In some cases these symptoms may be self-limiting, in other cases, babies may require intensive care unit support or hospitalisation.
Your doctor can discuss with you the risks of taking it while you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are taking CLOZARIL ODT or if you are about to be started on any new medicine.

If you plan to have surgery, tell your doctor that you are taking CLOZARIL ODT.

Things you should not do

- **Do not stop taking this medicine or lower the dosage, even if you are feeling better, without checking with your doctor.**

If you stop taking CLOZARIL ODT suddenly, your condition may worsen or you may have unwanted side effects such as excessive sweating, headache, nausea (feeling sick), vomiting and diarrhoea. If this medicine is stopped for any reason, your doctor will reduce the dose gradually, over a one-to-two-week period, to avoid side effects, before stopping the medicine completely.

- Do not take CLOZARIL ODT to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their condition seems similar to yours.

Things to be careful of

- Sudden unexplained death and heart attacks that may lead to death have been reported with CLOZARIL ODT.
- **Be careful when taking pain relievers, sleeping tablets or antihistamines (medicines for colds or allergies such as hay fever) while you are taking CLOZARIL ODT.**

CLOZARIL ODT can increase the drowsiness caused by medicines that affect your nervous system.

- CLOZARIL ODT may cause alteration in blood lipids. It may also cause weight gain. Your doctor may monitor your weight and blood lipid levels.
- CLOZARIL ODT can cause sleepiness, and remaining in bed for prolonged duration in combination with weight gain may lead to the formation of blood clots in some patients.
- If CLOZARIL ODT makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

CLOZARIL ODT may lower your blood pressure, especially at the start of treatment. These symptoms can usually be prevented by getting up slowly and flexing your leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

- **Make sure you keep cool in hot weather and keep warm in cool weather.**

As with other antipsychotic medicines, CLOZARIL ODT may affect the way your body reacts to temperature changes. It may prevent sweating, even during heatwaves. You may feel dizzy or faint if you are too hot.

To stay cool in hot weather, try to do the following:

- wear light clothing

- spend time in air-conditioned environments (or keep windows open and use electric fans)

- drink plenty of water

- take cool baths or showers and avoid hot baths and saunas

- try to restrict exercise or heavy work to cool parts of the day.

- **Inform your doctor if you stop smoking or change the number of caffeine-containing drinks that you have in one day.** These changes can affect the levels of this medicine in your blood.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CLOZARIL ODT affects you.

CLOZARIL ODT may cause tiredness, drowsiness, dizziness, light-headedness, fainting or seizures (fits) in some people, especially at the start of treatment. Seizures, drowsiness, fainting, muscle weakness may lead to falls.

Drinking alcohol

Tell your doctor if you drink alcohol.

You should not drink alcohol while you are taking CLOZARIL ODT.

CLOZARIL ODT may enhance the effects of alcohol.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C and protect from light.

Follow the instructions on the pack about how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

Remember that you must still have your blood tested for a month after stopping this medicine.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CLOZARIL ODT, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need

medical treatment if you get some of the side effects. Some of the side effects of CLOZARIL ODT can be relieved by changing the dose.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

You may be more likely to get some of the side effects of CLOZARIL ODT, such as rapid heartbeat, dizziness or light-headedness due to low blood pressure, constipation and difficulty urinating.

Do not be alarmed by this list of possible side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
- constipation or fewer bowel movements than normal (if it seems to be getting worse, check with your doctor immediately) - abdominal pain - nausea (feeling sick), vomiting - stomach discomfort, especially after a meal - diarrhoea - dry mouth - too much saliva - difficulty in swallowing - heartburn - tiredness, drowsiness - dizziness or light headedness when standing up - headache - agitation, confusion, disorientation, vivid dreams - blurred vision, difficulty in reading - weight gain, especially excessive weight gain - changes in sexual function - painful menstrual periods - repetitive and ritualised behaviour (obsessive compulsive symptoms) - obsessive thoughts - stuttering in speech - problems in passing or holding urine - dark urine - excessive urination - for males, dry orgasm (retrograde ejaculation) where very little or no semen is ejaculated as it enters the bladder instead. Urine will appear cloudy after an orgasm	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
- nocturnal bedwetting - increased or decreased sweating - skin reactions or change in skin colour - swelling of the glands in the cheeks - rash, purplish-red spots, fever or itching "butterfly" rash, joint pain, muscle pain, fever and fatigue - stuffy nose - sudden, uncontrollable increase in blood pressure - uncontrolled bending of the body to one side - a strong urge to move the legs (restless legs syndrome) with an unpleasant feeling in the legs	

Serious side effects

Serious side effects	What to do
- fainting or loss of consciousness - falls due to seizure, drowsiness, fainting, muscle weakness - crushing chest pain or chest pain - fever, sore throat, mouth ulcers, "flu-like" symptoms (chills, aching joints, swollen glands, lack of energy) or any other signs of infection - a fast or irregular heartbeat that is present even when you are resting, accompanied by rapid breathing, shortness of breath, swelling of the feet or legs, dizziness or light headedness, or chest pain - sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or troubled breathing - symptoms of neuroleptic malignant syndrome, with a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma - seizures (fits) - pain in the stomach, often accompanied by nausea with or without vomiting, leakage of diarrhoea or frequent and forceful bowel movements; bowel urges with no resulting movements.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
• severe or prolonged constipation, which may be accompanied by abdominal pain and bloating • signs of loss of blood sugar control (diabetes) such as excessive thirst, drinking or eating large amounts, weakness, passing large amounts of urine, dry mouth and skin, as CLOZARIL ODT may cause or worsen diabetes • spontaneous bleeding or bruising more easily than normal • signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness in an arm or leg • yellowing of the skin and/or eyes, sometimes accompanied by feeling sick and loss of appetite • difficulty in passing urine (water) or blood in the urine • loss of bladder control • muscle stiffness, muscle weakness, muscle spasms, or muscle pain • muscle spasms, fever, red-brown urine • rigidity or stiffness in the arms and legs, shaking or tremor, feeling unable to sit still • abnormal movements, inability to initiate movement, inability to remain motionless, inner feeling restlessness, stiff limbs, trembling hands • symptoms of tardive dyskinesia (uncontrolled involuntary purposeful movements of the tongue, face, mouth or jaw such as puffing of the cheeks, puckering of the mouth, chewing movements, grimacing, lip-smacking, rapid eye blinking) • persistent painful erection or prolonged erection • signs of respiratory tract infection or pneumonia such as fever, coughing, difficulty breathing, wheezing • signs of sepsis such as shivering, fever, rapid breathing and heart rate, a change in your mental	

Serious side effects	What to do
• state such as confusion or disorientation • chest pain, cough, hiccups, rapid breathing • varying degrees of pain in the chest and abdomen • pauses in breathing or periods of shallow breathing during sleep. The above are serious side effects that need medical attention.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CLOZARIL ODT contains

Active ingredient	clozapine 12.5 mg, 25 mg, 50 mg, 100 mg or 200 mg per tablet
Other ingredients (inactive ingredients)	• aspartame • crospovidone • magnesium stearate • mannitol • microcrystalline cellulose • peppermint flavour (ID 109068) • silicon dioxide • sodium stearyl fumarate • sunset yellow FCF • aluminium lake
Potential allergens	aspartame, mannitol (3.1 g per maximum daily dose of 900 mg clozapine), phenylalanine and trace quantities of sulfites. Products containing mannitol may have a laxative effect or cause diarrhoea.

Do not take this medicine if you are allergic to any of these ingredients.

What CLOZARIL ODT looks like

CLOZARIL ODT 12.5 mg: A peach, round, flat face radial edge tablet debossed with **C1** on one side of the tablet and **V** on the other side (AUST R 476048). Blister pack of 10 tablets.

CLOZARIL ODT 25 mg: A peach, round, flat face radial edge tablet debossed with **C2** on one side of the tablet and **V** on the other side (AUST R 476065). Blister pack of 100 tablets.

CLOZARIL ODT 50 mg: A peach, round, flat face radial edge tablet debossed with **C3** on one side of the tablet and **V** on the other side (AUST R 476066). Blister pack of 100 tablets.

CLOZARIL ODT 100 mg: A peach, round, flat face radial edge tablet debossed with **C4** on one side of the tablet and **V** on the other side (AUST R 476074). Blister pack of 100 tablets.

CLOZARIL ODT 200 mg: A peach, oval shaped, biconvex tablet debossed with **C5** on one side of the tablet and **V** on the other side (AUST R 476075). Blister pack of 100 tablets.

The quantity of tablets provided to you will be determined by your doctor.

Who distributes CLOZARIL ODT

Viatrix Pty Ltd
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Millers Point NSW 2000
www.viatrix.com.au
Phone: 1800 274 276

For medical enquiries, phone: 1800 931 383

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CLOZARIL ODT® is a Viatrix company trade mark

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