CLOPINE®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using CLOPINE?

CLOPINE contains the active ingredient clozapine. CLOPINE 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 using CLOPINE? in the full CMI.

2. What should I know before I use CLOPINE?

Do not use if you: have a problem with your intestines (including a medical condition known as paralytic ileus (where your bowel [intestine] does not work properly and you have severe constipation), have any heart problems, are unable to have a blood tests or have any disease of the blood, have an allergy to clozapine or any of the ingredients listed at the end of this CMI, have bone marrow disease, severe kidney disease, or liver disease, have problems with the circulatory (blood) or nervous system, have uncontrolled epilepsy (i.e. seizures), or have problems with alcohol or drug abuse.

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 use CLOPINE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLOPINE 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 use CLOPINE?

The usual starting dose is half of a 25 mg tablet once or twice on the first day, followed by one 25 mg tablet once or twice on the second day. If this dose is well tolerated, then the dose may be slowly increased. More instructions can be found in Section 4. How do I use CLOPINE? in the full CMI.

5. What should I know while using CLOPINE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using CLOPINE. • You must have strict and regular blood tests while taking CLOPINE. • Contact your doctor immediately if you develop a fever, signs and symptoms of an infection, notice any changes to your bowel movements (poo) or become pregnant.
Things you should not do	• Do not stop using 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 CLOPINE affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol. • You should not drink alcohol while you are taking CLOPINE.
Looking after your medicine	• Store CLOPINE tablets below 30°C. Protect from light. • Store CLOPINE suspension below 25°C.

For more information, see Section 5. What should I know while using CLOPINE? 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:, 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: constipation or fewer bowel movements than normal, abdominal pain or chest pain, a fast or irregular heartbeat and discomfort of the heart, fever, sore throat, mouth ulcers, "flu-like" symptoms, , 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)

Clozapine may cause slowing down of bowel (intestine) function, which may result in blockage, perforation or tissue damage and cause reactions such as constipation; nausea with or without vomiting; tenderness or swelling of the stomach, or bloating; gas/wind; foul-smelling breath; stomach pains/spasms; leakage of diarrhoea or frequent and forceful bowel movements (poo); bowel urges with no resulting movements; weight loss due to lack of appetite; lower back pain; pain or pressure in your bottom and bleeding from the bottom. These can lead to extremely severe outcomes. Your doctor must monitor bowel function before prescribing and during your therapy with CLOPINE. It is extremely important to immediately advise your doctor, coordinator, pharmacist, or any other health professional, of any changes to your bowel movements.

Myocarditis/pericarditis/cardiomyopathy:

CLOPINE may cause myocarditis (inflammation of heart muscle) and cardiomyopathy (disease of heart muscles), which may be fatal. These conditions, as well as pericarditis (inflammation of outer layer of the heart), have been reported in patients on clozapine. Please advise your doctor if you have, or previously had, any heart problems. Your doctor will monitor you during treatment. If required, your doctor may want to refer you to a cardiologist for further tests. If you feel any symptoms such as chest pain, speak to your doctor immediately.

CLOPINE®

Active ingredient(s): *Clozapine*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using CLOPINE?
2. What should I know before I use CLOPINE?
3. What if I am taking other medicines?
4. How do I use CLOPINE?
5. What should I know while using CLOPINE?
6. Are there any side effects?

1. Why am I using CLOPINE?

CLOPINE contains the active ingredient clozapine.

CLOPINE belongs to a group of medicines called antipsychotics. It helps to correct the chemical imbalances in the brain which may cause mental illness.

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

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

Ask your doctor if you have questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

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

2. What should I know before I use CLOPINE?

Warnings

Do not use CLOPINE:

- 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, lips, tongue or other parts of the body
  - rash, itching or hives on the skin.
- **if you have a low white blood cell count or if you have previously had a low white blood cell count caused by a medicine (except if it was following a treatment for cancer).**

  CLOPINE can cause agranulocytosis/ severe neutropenia This is a condition where the number of white blood cells is reduced. 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 CLOPINE.
- **if 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.

CLOPINE 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 use CLOPINE if :

- you have a problem with your intestines/bowel such as severe constipation, obstruction of the bowel, or any other condition which has affected your large bowel
- you experience a medical condition known as paralytic ileus (your intestines do not work properly and you have severe constipation)
- you have severe heart disease or myocarditis (an inflammation of the heart muscle) or any other heart problems. Symptoms may include chest pain, swelling of legs, ankles or feet, rapid or inconsistent heartbeat, or shortness of breath at rest.
- you are unable to have a blood test
- you have bone marrow disease
- you have severe kidney disease
- you have symptoms of active liver disease such as jaundice (yellowing of the skin and eyes, feeling sick, loss of appetite), liver failure or any other severe liver disease
- you have any disease of the blood which causes a reduced number or red blood cells or platelets
- you have problems with the circulatory (blood) or nervous system
- you have uncontrolled epilepsy (i.e. you still have some seizures)
- you have problems with alcohol or drug abuse.

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

- any form of heart disease or a family history of heart disease, including blood clots.
- Known history or family history of an abnormal conduction in the heart called "prolongation of the QT interval"
- stroke
- chronic constipation or problems with your intestines/bowel which needs to be treated before you start taking CLOPINE. Your doctor must also monitor bowel function while you are on CLOPINE
- inflammatory bowel disease (e.g. Crohn's disease)
- 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, or difficulty passing urine or unable to pass urine
- epilepsy that is under control (i.e. you no longer have seizures)
- diabetes or a family history of diabetes
- dementia, a condition in which there is a decline in all areas of mental ability.

Check with your doctor if you:

- take any medicines for any other condition
- will be in a hot environment or you do a lot of vigorous exercise. CLOPINE may make you sweat less, causing your body to overheat
- smoke and drink coffee. Sudden changes in your usual smoking or coffee drinking habits can also change the effects of CLOPINE.

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

Tell your doctor if you are pregnant or intend to become pregnant.

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

There are risks to the mother associated with untreated schizophrenia and with exposure to antipsychotics, including CLOPINE, during pregnancy.

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.

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

You should not breastfeed during CLOPINE treatment. This medicine may pass into breast milk and 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 may interfere with CLOPINE and affect how it works. These include:

- medicines that decrease the number of blood cells produced by your body
- other antipsychotic medicines use to treat mental illnesses
- medicines used to control mood swings or depression
- benzodiazepines and other medicines used to treat anxiety or help you sleep
- medicines used to control epilepsy such as 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)
- antihistamines, medicines used to control and prevent symptoms of allergies such as hayfever
- 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 heart beat
- medicines used to treat stomach ulcers such as cimetidine, pantoprazole, lansoprazole and omeprazole
- atropine, a medicine which may be used in some eye drops or cough preparations
- adrenaline, a drug used in emergency situations
- medicines used to treat fungal and viral infections
- birth control tablets, or hormone replacement therapy.

These medicines may be affected by CLOPINE or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

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

4. How do I use CLOPINE?

How much to use

- The usual starting dose is half of a 25 mg tablet (12.5 mg) taken once or twice on the first day, followed by one 25 mg tablet, once or twice on the second day.
- If this dose is well tolerated, then the dose may be slowly increased, usually to between 200 mg and 450 mg each day. 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, epilepsy or you are elderly, your doctor may start you on a lower dose and gradually increase the dose to prevent unwanted side effects.
- The dose may be altered by your doctor from time to time. Do not alter the dose yourself.
- It is important to keep taking your medicine even if you feel well.
- 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 CLOPINE

- **CLOPINE should be taken at the same time each day.**
- The total daily amount of CLOPINE is usually divided into two doses. However, if your total dose is 200 mg or less, your doctor may allow you to take the whole amount in one dose, usually in the evening.
- It does not matter if you take this medicine before or after food.

How to take CLOPINE

CLOPINE Tablets

Swallow CLOPINE tablets with water or other liquid.

CLOPINE Suspension

24 HOURS BEFORE THE FIRST USE:

1. Unscrew and remove the cap from the bottle.
2. Push the bottle adaptor into the top of the bottle. Once the adaptor is in place it stays there.
3. Replace the cap and ensure it is tightening.
4. Before the first dose only, SHAKE THE BOTTLE for 90 seconds.
5. Note the expiry date on the product label in permanent marker as 90 days from the date of opening.
6. Leave the bottle to stand for 24 hours to ensure the bubbles formed during shaking have dissipated.

IMMEDIATELY BEFORE DISPENSING DOSES:

1. Ensure the cap is tightening.
2. SHAKE THE BOTTLE for 10 seconds.
3. Remove the cap from the bottle.
4. Draw air into the oral dispenser (syringe) equivalent to the volume of the dose required.
5. Insert the oral dispenser into the opening of the bottle adaptor. Expel all the air from the oral dispenser into the bottle.
6. Invert the bottle and slowly draw up the amount prescribed by your doctor.
7. Turn the bottle upright and detach the oral dispenser from the bottle adaptor.
8. Invert the oral dispenser to prevent spillage. Swallow the contents of the oral dispenser.
9. Leave the bottle adaptor in place on the bottle.
10. Replace the bottle cap over the bottle adaptor after use.
11. Wash the oral dispenser with warm soapy water after each use. Then rinse well with water.

If you forget to use CLOPINE

If it is almost time for your next dose (within four 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 CLOPINE as you would normally.

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

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

If you have missed taking CLOPINE for more than two days, do not start taking it again before you contact your doctor.

To prevent unwanted side effects, your doctor will probably restart you on CLOPINE at a lower dose and increase it gradually back to your normal dose.

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

If you use too much CLOPINE

If you think that you have used too much CLOPINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 signs and symptoms of CLOPINE overdose include drowsiness, confusion, coma, light-headedness, shallow breathing or breathing more slowly, fast or irregular heart beat and dribbling. Occasionally, fits have also been reported.

5. What should I know while using CLOPINE?

Things you should do

Continue taking CLOPINE as long as your doctor tells you.

You must have strict and regular blood tests while taking CLOPINE. Your doctor will tell you when and how often you need to have your blood tested. This medicine can cause agranulocytosis. This is a condition where the number of white blood cells may be reduced.

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, agranulocytosis can be detected early, and if CLOPINE 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 CLOPINE.

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 CLOPINE 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 your white blood cells falls below a critical level, CLOPINE must be stopped immediately and you must never take any medicines containing clozapine again.

If you suffer from a high level of sugar in the blood (diabetes) your doctor may regularly check you level of sugar in the blood.

Watch for important side effects

If you develop symptoms such as severe constipation, obstruction of the intestine, or any changes to your intestine or poo habits, contact your doctor immediately as these may cause death.

If you develop a fast or irregular heartbeat that is present even when you are resting, accompanied by rapid breathing, shortness of breath, fever, flu-like symptoms, feel tired or faint, swelling of the feet or legs, swelling of the belly, cough, dizziness or light headedness, or chest pain, contact your doctor immediately as these may cause death.

These symptoms could be signs of myocarditis (inflammation of heart muscle), pericarditis (inflammation of outer layer of the heart), 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 CLOPINE.

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 CLOPINE.

Contact your doctor immediately if you:

- **develop a fever**

  Some patients develop fever in the first few weeks of taking CLOPINE. This is usually harmless. However, you must be checked carefully to make sure you do not have an infection, agranulocytosis, myocarditis or neuroleptic malignant syndrome, a reaction to some medicines which can cause a sudden increase in body temperature.

- **develop a sore throat, mouth ulcers, flu-like symptoms, or other signs of a cold or infection**

  This is necessary, as these symptoms may be an early sign of agranulocytosis, a problem with the blood resulting in an increased risk of infections. 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 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 older women. In very rare cases, it may be permanent. However, if detected early, these symptoms are usually reversible.

- **notice any changes to your gastrointestinal function such as stomach pain or difficulty having a bowel movement and they worry you. Clozapine may cause slowing down of bowel function, which may result in blockage, perforation, tissue damage and cause reactions such as constipation, nausea with or without vomiting, tenderness or swelling of the abdomen, or bloating, gas/wind, foul-smelling**

breath, severe dull to sharp stomach pains in the lower belly, leakage of diarrhoea or frequent and forceful bowel movements, bowel urges with no resulting movements, weight loss due to lack of appetite, 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 bowel function before prescribing and during your therapy with CLOPINE. It is extremely important to immediately advise your doctor, coordinator, pharmacist, or any other health professional, of any changes to your bowel movements.

Remind any doctor or dentist you visit that you are using CLOPINE or if you are about to be started on any new medicines.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking CLOPINE. It may affect other medicines used during surgery.

Be sure to keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

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

  If you stop taking CLOPINE suddenly, your condition may worsen or you may experience headache, nausea (feeling sick), vomiting or diarrhoea. Your doctor will gradually reduce the amount you take each day before stopping the medicine completely.
- **Do not take CLOPINE to treat any other complaints unless your doctor tells you to.**
- **Do not give your medicine to anyone else even if their condition seems similar to yours.**
- Do not let yourself run out of CLOPINE over the weekend or on holidays.

Things to be careful of

- Sudden unexplained death and heart attacks that may lead to death have been reported with CLOPINE.
- **Be careful when taking antihistamines (medicines used for hayfever, allergies or colds), sleeping tablets or tablets to relieve pain while taking CLOPINE.** CLOPINE can increase the drowsiness caused by medicines that affect your nervous system.
- CLOPINE may cause alteration in blood sugar and lipids. It may also cause weight gain. Your doctor may monitor your weight, blood sugar and lipid levels.
- CLOPINE 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 CLOPINE makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position**.
- **Make sure you keep cool in hot weather and keep warm in cool weather.** CLOPINE may affect the way your body reacts to temperature changes. It may prevent sweating and you may feel dizzy or faint if you are too hot.

Driving or using machines

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

CLOPINE may cause tiredness, drowsiness, light-headedness, dizziness, 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 CLOPINE. This medicine may enhance the effects of alcohol.

Looking after your medicine

- Store CLOPINE Tablets below 30°C. Protect from light.
- Store CLOPINE Suspension below 25°C. Recap the bottle tightly following each use.

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.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

When to discard your medicine

CLOPINE Suspension expires 90 days after first opening the bottle.

Getting rid of any unwanted medicine

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

Side effects

Side effects	What to do
• tiredness, drowsiness • dizziness, or light headedness when standing up • constipation or fewer bowel movements than normal (if it seems to be getting worse,	**Speak to your doctor if you have any of these side effects and they worry you.**

Side effects	What to do
check with your doctor immediately) • nausea, vomiting • stomach discomfort, especially after a meal • diarrhoea • dry mouth • too much saliva • difficulty in swallowing • swelling of the glands in the cheeks • heartburn • headache • mild fever • agitation, confusion, disorientation, vivid dreams • blurred vision • weight gain • changes in sexual function • painful menstrual periods • repetitive and ritualised behaviour (obsessive compulsive symptoms) • stuttering in speech • problems in passing or holding urine, dark urine, excessive urination, nocturnal bedwetting • 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 • increased or decreased sweating • skin reactions or change in skin colour • "butterfly" rash, joint pain, muscle pain, fever and fatigue • stuffy nose • 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
• severe dull to sharp 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, weight loss due to lack of appetite, lower back pain, pain or pressure in your bottom and bleeding from the bottom. • signs of allergic reaction such as itching, skin rash, hives, swelling of the face, lips or tongue, difficulty in swallowing or breathing • severe or prolonged constipation, which may be accompanied by tenderness or swelling of the stomach, or bloating • fainting or loss of consciousness • falls due to seizure, drowsiness, fainting, muscle weakness • 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, cough, shortness of breath, swelling of the feet or legs, swelling of the belly, dizziness or light headedness, or chest pain • 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 or fits • 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 • 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 • jaundice, yellowing of the skin and/or eyes • rash, purplish-red spots, usually associated with fever or itching • difficulty in passing urine (pee) or blood in the urine • loss of bladder control	**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
• muscle stiffness, muscle weakness, muscle spasms, or muscle pain • muscle spasms associated with 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 of restlessness, stiff limbs, trembling hands • symptoms of tardive dyskinesia (uncontrolled 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 state such as confusion or disorientation • chest pain, cough, hiccups, rapid breathing • varying degrees of pain in the chest and stomach • pauses in breathing or periods of shallow breathing during sleep.	

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.

Some side effects can only be found when your doctor does tests to check your progress.

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 CLOPINE contains

CLOPINE Tablets

Active ingredient (main ingredient)	CLOPINE 25 tablets contain 25 mg of clozapine. CLOPINE 50 tablets contain 50 mg of clozapine. CLOPINE 100 tablets contain 100 mg of clozapine. CLOPINE 200 tablets contain 200 mg of clozapine.
Other ingredients (inactive ingredients)	• povidone • microcrystalline cellulose • lactose monohydrate • sodium starch glycollate • magnesium stearate

CLOPINE Suspension

Active ingredient (main ingredient)	Each 1 mL of CLOPINE Suspension contains 50 mg of clozapine
Other ingredients (inactive ingredients)	• sorbitol solution (70% w/w) • povidone • monobasic sodium phosphate dihydrate • sodium methyl hydroxybenzoate • sodium propyl hydroxybenzoate, • xanthan gum • glycerol • hydrochloric acid • sodium hydroxide • purified water

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

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

What CLOPINE looks like

CLOPINE 25 are small, round, yellow tablets with "25" embossed over a breakline on one face, the other side is plain.

AUST R 67947 (blister pack); AUST R 93972 (bottles)

CLOPINE 50 are small, round, yellow tablets with "50" embossed over a breakline on one face, the other side is plain.

AUST R 95557 (blister pack); AUST R 95559 (bottles)

CLOPINE 100 are small, round, yellow tablets with "100" embossed over a breakline on one face, the other side is plain.

AUST R 67948 (blister pack); AUST R 93973 (bottles)

CLOPINE 200 are oval shaped yellow tablets with "200" embossed on one side and a breakline on the other side.

AUST R 95560 (blister pack); AUST R 95561 (bottles)

CLOPINE 25, CLOPINE 50, CLOPINE 100 and CLOPINE 200 are available in blister packs or bottles of 100 tablets.

CLOPINE Suspension is a yellow mixture in a glass amber bottle containing 100 mL of the suspension. This presentation is not available.

AUST R 142239

Who distributes CLOPINE

Douglas Pharmaceuticals Australia Pty Ltd

'The Cluster' Level 17

31 Queen Street

Melbourne, VIC 3000

medinfo@douglas.com.au

CLOPINE is a registered trademark of Douglas Pharmaceuticals Limited used under license.

This leaflet was prepared in February 2026.