

## Consumer Medicine Information

# CLOPINE®

***Clozapine 25, 50, 100 and 200 mg tablets***  
***Clozapine 50 mg/ml oral suspension***

---

## What is in this leaflet

---

This leaflet provides some useful information on **CLOPINE** tablets *and suspension*.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

---

## What CLOPINE is used for

---

**CLOPINE** tablets and suspension belong to the group of medicines known as antipsychotics. This group of medicines is mainly used in the treatment of schizophrenia. Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour.

This medicine is only used in patients with schizophrenia for whom other antipsychotic medicines have not worked or have caused severe side effects.

This medicine is thought to work by correcting the chemical imbalances in the brain, which may cause mental illness.

Your doctor may have prescribed it for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

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

---

## Before you take CLOPINE

---

### ***When you must not take it***

**Do not take this medicine if you have an allergy or have ever experienced an allergic reaction to the active ingredient, clozapine, or to any of the other ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to this medicine may include:

- breathing problems such as shortness of breath, wheezing, difficulty breathing
- skin rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body

**Do not take this medicine if you have a low white blood cell count, or if you have previously had a low white blood cell count caused by use of a medicine.**

**CLOPINE** can cause agranulocytosis. With this condition, the number of white blood cells (which are needed to fight infections) is reduced. If you have a low white blood cell count or have had one in the past, you must not take this medicine.

**Do not take CLOPINE if you have or have had any of the following medical conditions:**

- paralytic ileus, a small bowel condition
- bone marrow disorder
- Problems with your kidneys
- reduced function of the circulatory or nervous system
- symptoms of active liver disease such as jaundice (yellowing of the skin and eyes, feeling sick, loss of appetite) or liver failure
- uncontrolled epilepsy (fits or seizures)
- acute mental illness caused by alcohol or another drug.
- Inflammation of heart muscle (myocarditis)
- Any severe heart disorder

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

**Clopine must not be given to children under 16 years.**

**Do not take this medicine if the expiry date (EXP) shown on the outer container, on the blister strip or on the bottle has passed. Do not use if the tablets or suspension show signs of deterioration or if the packaging shows signs of tampering.**

If you take this medicine after the expiry date has passed, it may not work as well or you may feel unwell.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

### ***Before you start to take it***

**Tell your doctor if you have any allergies to:**

- any other medicines
- any other substances such as foods, preservatives or dyes.

**Tell your doctor if you are pregnant or are thinking of becoming pregnant during treatment with CLOPINE.**

There is limited information on the safety of clozapine in pregnancy. Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

**Make sure you use a contraceptive to prevent pregnancy during treatment with CLOPINE.**

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

It is recommended that you do not breast-feed while taking **CLOPINE**, as clozapine may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- heart disease or a family history of heart disease
- diseases of liver or kidneys or family history of liver and kidney problems
- orthostatic hypotension - feeling dizzy or faint when standing especially in the elderly
- anticholinergic effects -confusion and excitement especially in the elderly
- prostate problems especially in the elderly
- fits or epilepsy that is under control
- diabetes
- glaucoma (raised pressure in the eye)
- bone marrow disorder
- neuroleptic malignant syndrome (NMS) - a reaction to some medicines with a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure, which may lead to coma
- a condition called tardive dyskinesia characterised by uncontrollable twitching or jerking of the arms or legs
- chronic constipation.

Your doctor may want to take special precautions if you have any of these conditions.

**Tell your doctor if you smoke and how much coffee you drink. Nicotine and coffee can affect the amount of clozapine in your body. Sudden changes in your usual smoking or coffee drinking habits can also change the effects of this medicine.**

### ***Taking other medicines***

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

Some medicines and **CLOPINE** may interfere with each other. These include:

- medicines which may decrease the number of blood cells produced by your body
- drugs which depress bone marrow function eg. cotrimoxazole, chloramphenicol, sulphonamides, penicillamine, carbamazepine and antineoplastics should not be used concurrently.

- strong pain killers eg. morphine
- antihistamines - medicines used to control and prevent symptoms of allergies such as hay fever
- anticholinergic medicines used to relieve stomach cramps, spasms and travel sickness
- Parkinson's disease medicines
- high blood pressure medicines
- medicines used to treat a fast or irregular heart beat eg. digoxin
- atropine - a medicine which may be used in some eye drops or cough preparations
- adrenaline - a drug used in emergency situations
- warfarin or heparin - medicines used to prevent blood clots
- medicines used for stomach ulcers eg. cimetidine, omeprazole
- medicines used to treat bacterial infections eg. erythromycin, rifampicin
- epilepsy medicines eg phenytoin, carbamazepine, valproic acid
- other medicines for schizophrenia, mental disorders, depression or mood swings
- medicines to treat heart conditions
- sleep inducing medicines
- nicotine in medicines used to help you quit smoking eg. nicotine patches or chewing gum.
- medicines used to treat fungal and viral infections.
- St John's wort (*Hypericum perforatum*) - a herbal remedy.

These medicines may be affected by **CLOPINE** or may affect how well CLOPINE work. **Your doctor will advise you.**

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

**Be careful driving or operating machinery until you know how this medicine affects you.**

You may feel tired, drowsy, dizzy or you may feel faint while taking this medicine, especially during the early stages of treatment. If you have any of these symptoms, do not drive, operate machinery or do any tasks where you need to be alert.

There is no evidence that this medicine is addictive.

---

## **How to take CLOPINE**

---

Your dose of **CLOPINE** has been determined for you by your doctor. The dose will depend on how you respond to the medicine, other medicines you are taking, and other medical conditions that you may have. The dose may be altered from time to time.

**Carefully follow all directions given to you by your doctor.**

Their directions 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***

Your doctor will determine the most appropriate dose for you.

**Take CLOPINE exactly as prescribed by your doctor.**

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 effects.

**Do not take more or less CLOPINE than your doctor has prescribed.**

If you think the dose is too weak or too strong, talk to your doctor.

### ***How to take it***

The total daily amount of **CLOPINE** is usually divided into two doses. However, if your total dose is 200mg or less, your doctor may allow you to take the whole amount in one dose, usually in the evening.

**Swallow CLOPINE tablets with a full glass of water or other liquid.**

**CLOPINE suspension may be taken alone or in water if required.**

### ***When to take it***

**Take your medicine at about the same time each day.**

Taking your tablets or suspension at the same time each day will have the best effect. It will also help you to remember when to take the medicine.

It does not matter if you take this medicine before or after food.

### ***If you forget to take it***

**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 your medicine as you would normally.**

**If you miss a dose of CLOPINE, do not take a double dose to make up for the missed dose. If you have stopped 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### ***How long to take it***

**Take this medicine until your doctor tells you to stop.**

Your doctor will check your progress and decide how long to continue your treatment. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine **even if you feel well**.

**Do not lower the dosage, even if you are feeling better, unless your doctor tells you to do so.**

Your condition may worsen if you suddenly stop taking it. Your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

**Do not let yourself run out of over the weekend or on holidays.**

**If you have any concerns, talk to your doctor.**

**Do not give the medicine to anyone else even if their symptoms seem similar or they have the same condition as you.**

---

## **While you are taking CLOPINE**

---

### ***Things you must do***

**You must have strict and regular blood tests while taking this medicine.**

This medicine can cause agranulocytosis. This is a condition where the number of white blood cells (which are necessary to fight infection in your body) may be reduced. There is no way of knowing who is at risk of developing agranulocytosis.

Severe cases of agranulocytosis have resulted in deaths. However, with regular blood tests, agranulocytosis can be detected early, and if this medicine is stopped as soon as possible, the white blood cell numbers should return to normal.

**After starting on this medicine, you must have a blood test at least once a week for the first 18 weeks of treatment (this is when the risk of agranulocytosis is greatest), thereafter at least every 4 weeks for as long as you are taking this medicine, and for one month after stopping.**

Your doctor will advise if blood tests are required more often. These tests will tell the doctor if the white blood cell count is dropping.

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

**If the number of your white blood cells falls below a safe level, this medicine must be stopped immediately and you must never take any medicines containing clozapine again.**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking CLOPINE or if you are about to be started on any new medicines or if you plan to have surgery.**

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Be sure to keep all of your doctor's appointments so that your progress can be checked.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how this medicine affects you.**

**If the tablets or suspension make you feel dizzy, light-headed or faint, be careful when getting up from a sitting or lying position.**

This medicine may lower your blood pressure, especially at the start of treatment. Getting up slowly and flexing leg muscles and toes to get the blood circulating can usually prevent these symptoms. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

**Be careful when drinking alcohol or when taking antihistamines (medicines used for hay fever, allergies or colds), sleeping tablets or tablets to relieve pain while taking this medicine.**

Clozapine can increase drowsiness caused by alcohol and by medicines affecting your nervous system.

Clozapine may affect the way your body controls temperature, and it may prevent sweating even in very hot weather. Exercise, hot baths or saunas may make you feel dizzy or faint while you are taking this medicine.

---

## **Side effects**

---

All medicines have side effects. Some of these are serious most of them are not. You may need medical treatment if you get some of the side effects. Your doctor changing the dose can relieve some of the side effects of this medicine.

If you are over 65 years old, you may have an increased chance of getting side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist as soon as possible if you notice any of the following:**

- Feeling anxious
- vivid dreams
- blurred vision.
- constipation
- dizziness, fainting, light-headedness
- dry mouth
- headache
- increased or decreased sweating
- mild fever
- nausea, vomiting
- prolonged erection
- tiredness and drowsiness
- excessive saliva;
- weight gain

These are the more **common** side effects of this medicine.

**If any of the following happen, tell your doctor immediately or go to your nearest Accident & Emergency department or clinic:**

- develop a fast or irregular heart beat that is present even when you are resting, accompanied by rapid breathing, shortness of breath, dizziness or light headedness, or chest pain.  
These symptoms could be signs of **myocarditis**, an inflammation of the heart muscle, or another heart condition.
- sore throat, mouth ulcers, fever, any "flu-like" symptoms such as swollen glands or other signs of infection as these symptoms may be an early sign of **agranulocytosis**. Flu-like symptoms may also be a sign of myocarditis.
- signs of an allergic reaction such as itching, skin rash, hives, swelling of the face, lips or tongue, difficulty in swallowing or breathing
- signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision, slurred speech, numbness in an arm or leg
- confusion/disorientation
- loss of co-ordination
- seizures or fits
- jaundice, yellowing of the skin and/or eyes
- urinary problems - difficulty passing urine (water) or blood in the urine; loss of bladder control
- signs of loss of blood sugar control such as excessive thirst, passing large amounts of urine, dry mouth and skin
- persistent painful erection
- severe headache
- blurred vision or loss of vision
- muscle spasms, stiffness
- abdominal or lower back pain
- stomach pain accompanied by nausea and vomiting
- slurred speech
- unusual bruising or bleeding

These are **serious** side effects. You may need urgent medical treatment.

**If any of the following happen, STOP taking this medicine and tell your doctor immediately or go to your nearest Accident & Emergency department or clinic:**

- if you have muscle weakness, fever, fast or irregular heart beat and excessive sweating. These are symptoms of a very rare condition called **Neuroleptic Malignant Syndrome (NMS)** - a reaction to some medicines, which can cause a sudden increase in body temperature.
- if you have uncontrolled movements of the tongue, jaw (such as puffing at the cheeks, chewing movements, puckering of the mouth), face and mouth. These are symptoms of a very rare condition called **tardive dyskinesia** - a condition more likely to happen during long term treatment, especially in older women.

These conditions may develop in people who are taking other medicines in addition to **CLOPINE**, or may be due to medicines you were taking before starting **CLOPINE**. These symptoms **may** not be reversible.

These are **very serious** side effects. You may need urgent medical attention or hospitalisation.

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you unwell. Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

---

## Overdose

---

**Immediately contact a doctor or Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to the your nearest Accident and Emergency department or clinic, if you think that you or someone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.**

The most common signs and symptoms of clozapine overdose include: drowsiness, confusion and coma; light-headedness; shallow breathing or breathing more slowly; fast or irregular heartbeat and dribbling. Occasionally, fits have also been reported.

---

## Storage conditions

---

**Keep your medicine in the original container until it is time to take them.** If you take the tablets or suspension out of the original container they will not keep well.

**Keep your tablets in a cool dry place away from light where the temperature stays below 30°C.**

**Keep your suspension in a cool dry place away from light where the temperature stays below 25°C.**

**Do not store CLOPINE or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a windowsill.**

Heat and dampness can destroy medicines.

**As with all medicines, you should store them out of the reach of children.**

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

**Discard any remaining suspension 3 months after opening.**

### ***Disposal***

**If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any that are left over.**

---

## **Product Description**

---

### ***What it looks like***

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

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

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

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

**CLOPINE 50 mg/ml** - a free flowing yellow suspension.

### **Pack Sizes:**

**CLOPINE 25, CLOPINE 50, CLOPINE 100** and **CLOPINE 200** tablets come in packs of 50 or 100 tablets.

**CLOPINE 50 mg/ml Suspension** is available in a bottle containing 100 ml.

Your doctor will determine the quantity provided to you by the pharmacy.

### ***Ingredients***

Active ingredient: clozapine

Other ingredients: povidone, microcrystalline cellulose, lactose, sodium starch glycollate, magnesium stearate.

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

## SUPPLIER

Douglas Pharmaceuticals Ltd  
PO Box 45-027  
Te Atatu Peninsula  
Auckland 0651

Clopine® is a registered trademark of Douglas Pharmaceuticals Ltd.

16 February 2009

### Dispensing Instructions



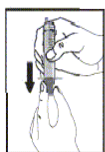
1. Shake the bottle until the suspension is thoroughly mixed..



2. Push down and turn the cap to open the bottle.



3. Push the bottle adaptor into the top of the bottle.



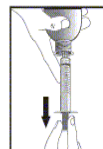
4. Fill the oral dispenser (syringe) with air.



5. Insert the oral dispenser into the opening of the bottle adaptor. Expel all the air from the oral dispenser into the bottle.



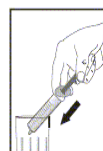
6. Turn the bottle upside down.



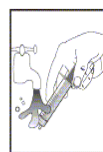
7. Withdraw the prescribed amount of Clopine Oral Suspension.



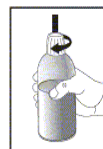
8. Turn the bottle upright and remove oral dispenser. Expel any large bubbles.



9. Swallow Clopine Oral Suspension directly from the oral dispenser or add the suspension to a glass with 200 ml of water. Stir and drink the entire mixture right away.



10. Wash the oral dispenser in warm soapy water after each use and rinse well with water. Leave to air dry.



11. Close the bottle with cap provided. The bottle adaptor does not need to be removed before closing.