

CLOPINE* TABLETS

Clozapine (25mg, 100mg)

What is in this leaflet

1. What Clopine Tablet is used for
2. How Clopine Tablet works
3. Before you use Clopine
4. How to use Clopine Tablet
5. While you are using it
6. Side effects
7. Storage and disposal of Clopine Tablet
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of Revision

What Clopine Tablet is used for

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

How Clopine Tablet works

CLOPINE belongs 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 thought to work by its action on brain chemicals.

Ask your doctor if you have any 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.

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

There is not enough information to recommend the use of this medicine in children under the age of 16 years.

Before you use Clopine Tablet

- When you must not use it

Do not take CLOPINE if you have an allergy to:

- any medicine containing clozapine
- 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.

Do not take Clopine tablet if you suffer or have ever suffered from severe constipation, obstruction of the bowel or any other condition which affected your large bowel.

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 a drug treatment.

CLOPINE can cause agranulocytosis. 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.

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

- bone marrow disorder
- severe liver or kidney disease
- severe heart disease
- problems with the circulatory (blood) 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.

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

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.

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

- Before you start to use it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

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

- heart disease or a family history of heart disease, liver or kidney problems
- fits or epilepsy that is under control
- diabetes
- prostate enlargement
- glaucoma (raised pressure in the eye)
- paralytic ileus, a condition in which the small bowel does not work properly
- 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).

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking CLOPINE.

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

- 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.

Tell your doctor or pharmacist if you are taking or have recently taken medicines which cause constipation (such as anticholinergic, which are used to relieve stomach cramps, spasms and travel sickness).

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

- bone marrow depressants, medicines which may decrease the number of blood cells produced by your body
- strong pain killers such as morphine
- antihistamines, medicines used to control and prevent symptoms of 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
- medicines used to treat a fast or irregular heart beat
- atropine, a medicine which may be used in some eye drops or cough preparations
- adrenaline, a drug used in emergency situations
- warfarin, a medicine used to prevent blood clots

CLOPINE* TABLETS

Clozapine (25mg, 100mg)

- medicines used for stomach ulcers eg cimetidine, omeprazole
- medicines used to treat bacterial infections eg erythromycin, rifampicin
- medicines used to treat epilepsy eg phenytoin, carbamazepine, valproic acid
- other medicines for schizophrenia, mental disorders or depression
- medicines to treat heart conditions
- medicines to calm you and help you sleep
- 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 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.

How to use Clopine Tablet

- How much to use

Follow all directions given to you by your doctor or 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.

Take CLOPINE exactly as prescribed by your doctor to help prevent unwanted side effects.

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.

When you first start taking CLOPINE, the usual dose is half a 25 mg tablet (12.5 mg) taken once or twice on the first day, followed by one or two 25 mg tablets taken 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 a day. However, some people may need a higher dose.

Your doctor will determine the most appropriate dose for you. Once the maximum benefit is achieved, your doctor may reduce the dose 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 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.

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.

Swallow CLOPINE tablets with a full glass of water.

- When to use it

Take your medicine at about the same time each day.

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

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

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

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.

- If you forget to use 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 tablets as you would normally.

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

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

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much CLOPINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. The most common signs and symptoms of CLOPINE overdose include: drowsiness, confusion and coma; lightheadedness; shallow breathing or breathing more slowly; fast or irregular heart beat and dribbling. Occasionally, fits have also been reported.

While you are using it

- Things you must do

You must have strict and regular blood tests while taking CLOPINE. CLOPINE 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.

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.

After starting on CLOPINE, 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 CLOPINE, and for one month after stopping the medicine.

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 critical level, CLOPINE must be stopped immediately and you must never take any medicines containing clozapine again.

Tell your doctor or pharmacist if you have experienced constipation, abdominal pain, abdominal tenderness, fever, bloating and/

CLOPINE* TABLETS

Clozapine (25mg, 100mg)

or bloody diarrhea. Your doctor will need to examine you.

Watch for important side effects:

If you 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, contact your doctor immediately. 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.

If at any stage during treatment with CLOPINE you develop a sore throat, mouth ulcers, fever, flu-like symptoms or other signs of infection, you must contact your doctor immediately.

This is necessary, as these symptoms may be an early sign of agranulocytosis. Flu-like symptoms may also be a sign of myocarditis.

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.

If you notice any uncontrolled movements of the tongue, face, mouth or jaw, such as puffing of the cheeks, puckering of the mouth or chewing movements, tell your doctor immediately.

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.

If you are about to be started on any new medicines, remind your doctor and pharmacist that you are taking CLOPINE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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.

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 must not do

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 they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

- Things to be careful of

Be careful driving or operating machinery until you know how CLOPINE affects you.

This medicine may cause drowsiness, light-headedness or dizziness in some people. If you do have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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

If you drink alcohol, or take some medicines, drowsiness, dizziness or light-headedness may be worse.

This medicine 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

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Clopine Tablet.

This medicine helps most people with schizophrenia, but it may have unwanted side effects in a few people. All medicines have side effects.

Sometimes these are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years old, you may have an increased chance of getting side effects. Do not be alarmed by the following lists of side effects.

You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist if you notice any of the following and they worry you:

- tiredness and drowsiness
- dizziness, fainting, light-headedness
- dribbling or excess salivation
- dry mouth
- weight gain
- nausea, vomiting
- constipation
- mild fever
- headache
- anxiety, vivid dreams
- excessive sweating
- prolonged erection
- blurred vision
- Abdominal pain, cramping, swollen abdomen, vomiting, constipation and failure to pass gas which may be signs and symptoms of bowel obstruction

The above list includes the more common side effects of your medicine. They are usually mild. If any of the following happen, tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- sore throat, mouth ulcers, fever, any "flu-like" symptoms such as swollen glands or other signs of infection
- signs of an allergic reaction such as itching, skin rash, hives, swelling of the face, lips or tongue, difficulty in swallowing or breathing
- a sudden increase in body temperature, sweating, fast heart beat and muscle stiffness which may be symptoms of neuroleptic malignant syndrome
- fast or irregular heart beat even when you are resting
- 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
- 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.

CLOPINE* TABLETS

Clozapine (25mg, 100mg)

- confusion/disorientation
- loss of co-ordination, tremor or rigidity
- 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
- loss of vision
- muscle spasms, stiffness
- abdominal or lower back pain
- stomach pain accompanied by nausea and vomiting
- slurred speech
- unusual bruising or bleeding
- chest pain.

The above list includes serious side effects which may require medical attention.

Tell your doctor or pharmacist if you notice anything else that is making you unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Clopine Tablet

- Storage

Keep your tablets in the original packaging until it is time to take them.

If you take the tablets out of the original packaging they will not keep well.

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

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

Heat and dampness can destroy some medicines.

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

- Disposal

If your doctor tells you to stop taking this medicine or the tablets have passed their expiry date, ask your pharmacist what to do

with any that are left over. Remember that you must still have your blood tested for a month after stopping this medicine.

Product Description

- What it looks like

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

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

Pack Sizes:

Both CLOPINE 25 and CLOPINE 100 come in blister of 50 or 100 tablets. The quantity provided to you by the pharmacy will be determined by your doctor.

- Ingredients

- Active ingredient(s)

Clozapine

- Inactive ingredients

Microcrystalline cellulose, sodium starch glycollate, Povidone, Magnesium stearate, Lactose, Purified water

- MAL number:

Clopine 25 mg Tablets

MAL06061680AZ

Clopine 100 mg Tablets

MAL06061681AZ

*Clopine is a registered trademark in New Zealand and Malaysia.

Manufacturer

Douglas Manufacturing Ltd,
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Product Registration Holder

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