

CLOPINE®

Tablets and Suspension

Clozapine (KLOE-za-peen)

Consumer Medicine Information

What is in this leaflet

This leaflet provides some useful information about CLOPINE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CLOPINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CLOPINE is used for

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

This medicine 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 correcting the chemical imbalances in the brain which may cause mental illness.

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 take CLOPINE

When you must not take 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 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 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.

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

- any disease of the blood which causes a reduced number of red blood cells or platelets
- bone marrow disorder
- severe 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), liver failure or any other severe liver disease
- uncontrolled epilepsy (fits or seizures)
- acute mental illness caused by alcohol or another drug
- paralytic ileus, a condition in which the small and/or large bowel does not work properly, including severe constipation or obstruction.

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 take 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.

There is limited information on the safety of CLOPINE 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.

You should not breast feed during CLOPINE treatment. This medicine may pass into breast milk and affect your baby.

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

- heart disease or a family history of heart disease
- stroke
- liver or kidney problems
- fits or epilepsy that is under control
- diabetes or a family history of diabetes
- prostate enlargement
- glaucoma (raised pressure in the eye)
- neuroleptic malignant syndrome, 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
- 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)

- chronic constipation.
- dementia, a condition in which there is a decline in all areas of mental ability
- any other serious medical condition.

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

Tell your doctor if you 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.

Tell your doctor if you smoke and how much coffee you drink.

Smoking and caffeine can affect how CLOPINE® affects your body. Sudden changes in your usual smoking or coffee drinking habits can also change how much CLOPINE you need.

Tell your doctor if you are lactose intolerant.

This medicine contains lactose.

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

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

- 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 such as digoxin
- 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
- medicines used for stomach ulcers and reflux oesophagitis such as cimetidine, pantoprazole, lansoprazole and omeprazole
- medicines used to treat bacterial infections such as erythromycin, clarithromycin, azithromycin, norfloxacin, rifampicin, and ciprofloxacin
- medicines used to treat epilepsy such as phenytoin, carbamazepine and valproic acid
- other medicines for mental disorders such as schizophrenia, mood swings or depression
- medicines to calm you and help you sleep such as benzodiazepines
- medicines used to treat fungal and viral infections
- St John's wort (*Hypericum perforatum*), a herbal remedy
- birth-control tablets

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 take CLOPINE

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.

How much to take

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 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 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 200 mg or less, your doctor may allow you to take the whole

amount in one dose, usually in the evening.

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 tightened.
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 tightened.
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.

When to take it:

Take your medicine at about the same time each day.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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, coma, light-headedness, shallow breathing or breathing more slowly, fast or irregular heart beat and dribbling. Occasionally, fits have also been reported.

While you are taking CLOPINE

Things you must do

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

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.

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.

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.

Make sure you use a contraceptive to prevent pregnancy during treatment with CLOPINE. If you become pregnant while taking this medicine, tell your doctor immediately.

Your doctor can discuss with you the risks of taking it while you are pregnant.

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

This medicine 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. 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.

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.

Keep cool in hot weather and keep warm in cool weather.

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.

Tell 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.

Side effects

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

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:

- tiredness, drowsiness or fatigue
- dizziness, fainting, light-headedness
- too much saliva
- difficulty in swallowing
- dry mouth
- nasal congestion
- weight gain
- nausea, vomiting
- constipation
- diarrhoea

- abdominal discomfort, heartburn or dyspepsia
- changes in sexual function
- painful menstrual periods
- problems in passing or holding urine, dark urine, excessive urination, nocturnal bedwetting
- skin reactions or change in the colour of the skin
- mild fever
- headache
- agitation, confusion,
- increased or decreased sweating
- blurred vision
- stuttering
- rash, purplish-red spots usually associated with fever or itching
- "butterfly" rash, joint pain, muscle pain, fever and fatigue
- uncontrolled bending of the body to one side
- 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

If any of the following happen, tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- fainting or loss of consciousness
- falls due to seizure, drowsiness, fainting, muscle weakness
- chest pain
- 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, accompanied by rapid breathing, shortness of breath, swelling of

- the feet or legs, dizziness or light headedness, or chest pain
- 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, chest pain or shortness of breath.
- 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.
- signs of pneumonia or lower respiratory tract infection such as difficulty breathing, coughing, and chest pain
- signs of sepsis such as shivering, fever, rapid breathing and heart rate, a change in your mental state such as confusion or disorientation
- 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
- muscle spasms associated with fever and/or red-brown urine
- loss of co-ordination, shaking or tremor, feeling unable to sit still, rigidity or muscle stiffness/spasms/weakness or pain
- persistent painful erection or prolonged erection
- abdominal or lower back pain
- stomach pain accompanied by nausea and vomiting
- severe or prolonged constipation, which may be accompanied by abdominal pain and bloating

- unusual bruising or bleeding
- cough, hiccups, rapid breathing, chest pain which can be associated with abdomen pain
- pauses in breathing or periods of shallow breathing during sleep.

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.

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

These tests could show a reduction in white blood cells, red blood cells or changes in blood platelet levels. These tests could also show a change in liver enzymes, blood sugar and lipid levels.

After using CLOPINE

Storage

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

Tablets and Suspension:

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

Store the CLOPINE Suspension below 25°C. Recap the bottle tightly following each use. Discard the bottle 90 days after it has been opened.

Do not store CLOPINE tablets or suspension 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 CLOPINE or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

CLOPINE Suspension expires 90 days after first opening the bottle.

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 50 are small, round, yellow tablets with "50" 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.

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

CLOPINE Suspension is a yellow mixture called a suspension in a glass amber bottle containing 100 mLs.

Pack Sizes:

CLOPINE 25, CLOPINE50, CLOPINE 100 and CLOPINE 200 come in blister packs or bottles of 100 tablets.

CLOPINE Suspension comes in a 125mL bottle containing 100mLs of the suspension.

The quantity provided to you by the pharmacy will be determined by your doctor.

Ingredients

CLOPINE Tablets:

Active ingredient:

CLOPINE 25 tablets contain 25 mg of clozapine. CLOPINE 50 tablets contain 50 mg of clozapine. CLOPINE 100 tablets contain 100mg of clozapine. CLOPINE 200 tablets contain 200 mg of clozapine.

CLOPINE tablets also contain:

- povidone
- microcrystalline cellulose
- lactose monohydrate
- sodium starch glycollate
- magnesium stearate.

CLOPINE Suspension:

Active ingredient:

Each 1 ml of CLOPINE Suspension contains 50mg of clozapine.

CLOPINE suspension also contains:

- sorbitol solution (70 per cent)
- povidone
- monobasic sodium phosphate dihydrate
- sodium methyl hydroxybenzoate
- sodium propyl hydroxybenzoate,
- xanthan gum
- glycerol
- purified water

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

Supplier

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3, 500 Collins St
Melbourne Victoria 3000
Australia

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CLOPINE 25 in blister packs
AUST R 67947

CLOPINE 25 in bottles
AUST R 93972

CLOPINE 50 in blister packs
AUST R 95557

CLOPINE 50 in bottles
AUST R 95559

CLOPINE 100 in blister packs
AUST R 67948

CLOPINE 100 in bottles
AUST R 93973

CLOPINE 200 in blister packs
AUST R 95560

CLOPINE 200 in bottles
AUST R 95561

CLOPINE Suspension
AUST R 142239

This leaflet was updated in November 2017.