

# ZAPINE

Clozapine (100 mg)

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## What Zapine is used for

Zapine is used to treat schizophrenia. Schizophrenia is a mental illness that affects the way a person thinks and behaves.

This medicine is used for schizophrenic patients only when other medicines have not worked or have caused severe side effects.

## How Zapine works

Zapine contains a substance called Clozapine. It belongs to a group of medicines called antipsychotics. This medicine is thought to work by correcting the chemical imbalances in the brain, which may cause mental illness.

## Before you use Zapine

- When you must not use it

### Do not take Zapine:

If you are allergic to clozapine, or to any of the other ingredients of Zapine (see section Ingredients).

Symptoms of an allergic reaction can include:

- breathing problems such as shortness of breath, wheezing, difficulty breathing
- Itchy skin rash or hives
- swelling of the face, mouth and 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.

Zapine can cause agranulocytosis, a condition which white blood cells

(which are needed to fight infections) is too low.

Do not take Zapine if you have any of the following disease:

- Bone marrow disorder
- Problems with your kidneys
- Reduced function of the circulatory or nervous system
- Active liver disease associated with jaundice or liver failure
- Uncontrolled epilepsy (fits or seizures)
- Acute mental illness caused by alcohol or another drug.
- Heart disorders
- If you are unconscious or in a coma.
- Before you start to use it

*Tell your doctor if you:*

- Allergic to any other medicines
- Allergic to any other substances such as foods, preservatives or dyes.
- Have or have family history of any following medical conditions:
  - Heart diseases
  - Liver diseases
  - Kidneys diseases
  - Orthostatic hypotension (feeling dizzy or faint when standing especially in the elderly)
  - Prostate problems
  - 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 heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma)
  - Tardive dyskinesia (uncontrolled muscle movements of the face, tongue, jaws, trunk, and limbs)
  - Chronic constipation.

- Smoke and how much coffee you drink. Nicotine and coffee can affect the amount of clozapine in your body. Sudden changes in your smoking or coffee drinking habits can also change the effects of this medicine.

## Pregnancy and breast feeding

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. Do not take Zapine until you and your doctor have discussed the risks and benefits involved.

The following *extrapyramidal* and/or *withdrawal symptoms* may occur in newborn babies, of mothers that have used Zapine in the last trimester (last three months of their pregnancy): agitation, muscle stiffness and/or weakness, shaking, sleepiness, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Do not use this medicine if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

## Switching from a previous neuroleptic therapy to clozapine

You need to stop from taking your previous medication by reducing its dose over a period of 1 week.

Once the neuroleptic has been completely discontinued for at least 24 hours, clozapine treatment can be started as described above. Your doctor will know when it is safe to start Zapine on you.

It is generally recommended that clozapine should not be used in combination with other neuroleptics.

### - Taking other medicines

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

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

- Which depress bone marrow function
- Antihistamines (used to control and prevent symptoms of allergies)
- Anticholinergic (used to relieve stomach cramps, spasms and travel sickness)
- high blood pressure medicines
- anaesthetics - a drug used during operations
- 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.

These medicines may be affected by Zapine tablets or may affect how well Zapine tablets 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.

### How to use Zapine tablets

#### - How much to use

The dosage must be adjusted individually. For each patient the lowest effective dose should be used.

The total amount of Zapine you take each day is usually divided into two doses. If you have to divide your dose, you should take the larger dose at bed time. However, if your total daily dose is not over 200 mg, it is not necessary to divide the dose. In this case, it is usually taken in the evening.

When you first start taking Zapine, the usual dose is half a 25 mg tablet (12.5 mg) taken once or twice on the first day.

If this dose is well tolerated, it may be increased gradually. However, some people may need a higher dose. The maximum permissible dose is 900 mg per day. Once the maximum benefit is achieved, your doctor may reduce the dose gradually to a lower level. Your doctor will determine the most appropriate dose for you.

#### *Use in the elderly*

Treatment usually begins with a lower dose (e.g. 12.5 mg daily), which is then gradually increased.

#### - 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.

#### - How long to use it

Do not lower the dosage or stop taking this medicine, even if you are feeling better, unless your doctor tells you to do so.

#### *Ending therapy*

If your doctor plan to terminate this clozapine therapy, your dose may be reduced over a 1-to-2 week period.

#### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

Contact your doctor as soon as possible if you have not taken any Zapine for more than 48 hours. To prevent unwanted side effects, your doctor will probably restart you on Zapine tablets at a lower dose and increase it gradually back to your normal dose.

#### - If you use too much (overdose)

If overdosage occurs, in all cases treatment should be discontinued and you should immediately contact your doctor or go to your nearest hospital emergency department.

Overdose of Zapine could cause drowsiness, confusion and coma; light-headedness; breathing difficulty; fast or irregular heartbeat.

### While you are using it

#### - Things you must do

Tell all of the doctors and pharmacists who are treating you that you are taking ZAPINE or if you are about to start on any new medicines or if you plan to have surgery.

You must have:

- Regular and strict blood tests while taking ZAPINE.
  - At least once a week for the first 18 weeks of treatment
  - At least every 4 weeks for as long as you are taking this medicine
  - One month after stopping.

Zapine can cause agranulocytosis (see also section **Side effects**). 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.

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.

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.

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 you must not do

Do not:

- Stop taking the medicine unless advised by your doctor.
- Take any new medicines without consulting your doctor.
- Give Zapine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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

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 lightheaded or faint. 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 but most of them are not. You may need medical treatment if you get some of the side effects. By changing the dose some of the side effects of this medicine can be relieved.

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.

**Haematological (blood-related disease)**

- Granulocytopenia & Agranulocytosis (Decreased of cells that combat infection). If you have sore throat, mouth ulcer, fever, any "flulike" symptoms such as swollen glands or other signs of infection, contact your doctor immediately (see also Things you must do).
- Thrombocytopenia - deficiency in platelet; agent to clot the blood (very rare)

**Central Nervous System**

- Fatigue
- Drowsiness
- Headache
- Seizure
- Confusion (rare)
- Restlessness (rare)
- Agitation (rare)
- Tardive dyskinesia (very rare)

**Neuroleptic Malignant Syndrome**

If you have a sudden rapid increase in body temperature, rigid muscles, excessive sweating, rapid heartbeat and confusion, which may lead to unconsciousness, contact your doctor immediately.

**Autonomic Nervous Syndrome**

- Dry mouth
- Blurred vision
- Increased or decreased sweating
- Excessive saliva

**Cardiovascular System**

- Increased heartbeat
- Orthostatic hypotension
- Fainting
- Irregular heartbeat
- Myocarditis - Inflammation of heart muscle or another heart conditions
- Hypertension (rare)
- Cardiomyopathy – damaged or weakened heart muscle (very rare)

If you have fast and irregular heartbeat, even when you are at rest, palpitations, breathing problems, flu-like symptoms, chest pain or unexplained tiredness, contact your doctor immediately.

**Respiratory System**

- Difficulty to breath (very rare)

**Gastrointestinal System**

- Nausea
- Vomiting
- Constipation
- Jaundice (Rare)
- Infection of liver (rare)
- Difficulty of swallowing (rare)
- Hyperglycaemia (increased sugar in blood) (rare)
- Ileus- obstruction of intestine (very rare)

**Genitourinary System**

- Loss of bladder control
- Persistent painful erection (rare)

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

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.my](http://portal.bpfk.my) (Consumers → Reporting)

**Storage and disposal of Zapine tablets**

-Storage

Keep medicine out of the reach and sight of children.

Store at temperature below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product description**

-What it looks like

It is a pale-yellow, round, bevel-edge flat tablet, with a line scored on one side and a (ST 364) on the other side.

-Ingredients

- Active ingredient:  
Clozapine.

- Inactive ingredients:  
Corn starch Lactose monohydrate,  
Magnesium stearate and Povidone.

-MAL number

MAL07090952A

**Manufacturer**

Taiwan Biotech Co., Ltd.,  
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**Date of revision**

24/07/2015

**Serial Number**

BPFK(R4/1)230715/00219