

Package leaflet: Information for the patient

Zolapine 5 mg/ Zolapine 10 mg / Zolapine 15 mg/ Zolapine 20 mg

Orodispersible tablets

Olanzapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Zolapine is and what it is used for
2. What you need to know before you take Zolapine
3. How to take Zolapine
4. Possible side effects
5. How to store Zolapine
6. Contents of the pack and other information

1. What Zolapine is and what it is used for

Zolapine contains the active substance olanzapine. Olanzapine belongs to a group of medicines called antipsychotics and is used to treat the following conditions:

- Schizophrenia, a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.
- Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

Zolapine has been shown to prevent recurrence of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

2. What you need to know before you take Zolapine

Do not take Zolapine:

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath.
- If you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).

If any of the above applies to you, do not take Zolapine and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

- The use of Zolapine in elderly patients with dementia is not recommended as it may have serious side effects.
- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Zolapine consult your doctor.
- Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.
- Weight gain has been seen in patients taking Zolapine. You and your doctor should check your weight regularly. Consider referral to a dietitian or help with a diet plan if necessary.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking Zolapine. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking olanzapine and regularly during treatment.
- Tell the doctor if you or someone else in your family has a history of blood clots, as medicines like these have been associated with the formation of blood clots.

If you suffer from any of the following illnesses tell your doctor as soon as possible:

- Stroke or “mini” stroke (temporary symptoms of stroke)
- Parkinson’s disease
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Liver or kidney disease
- Blood disorders
- Heart disease
- Diabetes
- Seizures
- If you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)

If you suffer from dementia, you or your carer/relative should consult your doctor if you have ever had a stroke or “mini” stroke.

As a routine precaution, if you are over 65 years of age your blood pressure may be monitored by your doctor.

Children and adolescents under 18 years of age

Zolapine is not for patients who are under 18 years.

Other medicines and Zolapine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You might feel drowsy if Zolapine is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

In particular, tell your doctor if you are taking:

- medicines for Parkinson’s disease.
- carbamazepine (an anti-epileptic and mood stabiliser), fluvoxamine (an antidepressant) or ciprofloxacin (an antibiotic) - it may be necessary to change your Zolapine dose.

Zolapine with alcohol

Do not drink any alcohol if you have been given Zolapine as together with alcohol it may make you feel drowsy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You should not be given this medicine when breast-feeding, as small amounts of Zolapine can pass into breast milk.

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

Driving and using machines

There is a risk of feeling drowsy when you are given Zolapine. If you experience this symptom, do not drive or use tools or machines, and tell your doctor.

Zolapine contains aspartame and mannitol

Patients who cannot take phenylalanine should note that Zolapine contains aspartame, which is a source of phenylalanine. It may be harmful for people with phenylketonuria.

Patients who cannot take mannitol should note that Zolapine contains mannitol.

3. How to take Zolapine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many Zolapine tablets to take and how long you should continue to take them. The daily dose of Zolapine is between 5 mg and 20 mg. Consult your doctor if your symptoms return but do not stop taking Zolapine unless your doctor tells you to.

You should take your Zolapine tablets once a day following the advice of your doctor. Try to take your tablets at the same time each day. It does not matter whether you take them with or without food. Zolapine orodispersible tablets are for oral use.

Zolapine tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

- Gently push the tablet out.
- Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.

You can also place the tablet in a full glass or cup of water, orange juice, apple juice, milk or coffee, and stir. With some drinks, the mixture may change color and possibly become cloudy. Drink it straight away.

If you take more Zolapine than you should

Patients who have taken more Zolapine than they should have experienced the following symptoms: fast heart beat, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness.

Other symptoms may be: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart. Contact your doctor straight away if you experience any of the above symptoms. Show the doctor your pack of tablets.

If you forget to take Zolapine

If you forget to take a dose of this medicine, take it as soon as you remember and then take the next dose at its usual time. If it is almost time for your next dose you should simply take the next tablet at the usual time. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Zolapine

Do not stop taking your medicine unless your doctor tells you to. Always take this medicine, even if you are feeling well.

If you suddenly stop taking Zolapine, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you to reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have :

- unusual movement (a common side effect that may affect up to 1 in 10 people) mainly of the face or tongue.
- blood clots in the veins (an uncommon side effect that may affect up to 1 in 100 people) especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. (the frequency of this side effect cannot be estimated from the available data).

Very common side effects (may affect more than 1 in 10 people) include: weight gain, sleepiness, and increases in levels of prolactin in the blood. In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.

Common side effects (may affect up to 1 in 10 people) include: changes in the levels of some blood cells, circulating fats and early in treatment, temporary increases in liver enzymes; increases in the level of sugars in the blood and urine; increases in levels of uric acid and creatine phosphokinase in the blood; feeling more hungry; dizziness; restlessness; tremor; unusual movements (dyskinesias); constipation; dry mouth; rash; loss of strength; extreme tiredness; water retention leading to swelling of the hands, ankles or feet; fever; joint pain and sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Uncommon side effects (may affect up to 1 in 100 people) include: hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasms (including eye movements); restless legs syndrome; problems with speech; stuttering; slow heart rate; sensitivity to sunlight; bleeding from the nose; abdominal distension; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence or decrease in menstrual periods; and changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Rare side effects include (may affect up to 1 in 1000 people) : lowering of normal body temperature; abnormal rhythms of the heart; sudden unexplained death; inflammation of the pancreas causing severe stomach pain, fever and sickness; liver disease appearing as yellowing of the skin and white parts of the eyes; muscle disease presenting as unexplained aches and pains; and prolonged and/or painful erection.

Very rare side effects include: serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen on blood tests and an increase in a type of white blood cells (eosinophilia).

While taking Zolapine, elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of patients.

In patients with Parkinson's disease Zolapine may worsen the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zolapine

- Keep this medicine out of the sight and reach of children.
- Do not use Zolapine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Store in the original package.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What Zolapine contains

The active substance in Zolapine is olanzapine.

Each Zolapine orodispersible tablet contains either 5 mg, 10 mg, 15 mg or 20 mg of the active substance.

The other ingredients are: low-substituted hydroxypropyl cellulose, mannitol, crospovidone, aspartame, magnesium stearate, and talc.

What Zolapine looks like and contents of the pack

Zolapine tablets are yellow orodispersible tablets.

Orodispersible tablet is the technical name for a tablet which dissolves directly in your mouth, so that it can be easily swallowed.

Zolapine is available in packs containing 30 tablets.

Not all strengths may be marketed in all countries.

Marketing Authorisation Holder and Manufacturer

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Registration No for Zolapine 10 mg tablets: 169415/1
Registration No for Zolapine 15 mg tablets: 24818/1
Registration No for Zolapine 20 mg tablets: 24918/1

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

**Council of Arab Health Ministers
Union of Arab Pharmacists**

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