



ZYRWAN[®] OD 5 mg, orodispersible tablets

ZYRWAN[®] OD 10 mg, orodispersible tablets

ZYRWAN[®] OD 15 mg, orodispersible tablets

ZYRWAN[®] OD 20 mg, orodispersible tablets

Olanzapine

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Zyrwan OD is and what it is used for
2. Before you take Zyrwan OD
3. How to take Zyrwan OD
4. Possible side effects
5. How to store Zyrwan OD
6. Further information

1. What Zyrwan OD is and what it is used for

Zyrwan OD belongs to a group of medicines called antipsychotics.

Zyrwan OD is used to treat 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.

Zyrwan OD is used to treat a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with this condition.

2. Before you take Zyrwan OD

Do not take Zyrwan OD

- if you are allergic (hypersensitive) to olanzapine or any of the other ingredients of **Zyrwan OD**. An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.
- if you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).

Take special care with Zyrwan OD

- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given **Zyrwan OD** tell 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.
- The use of **Zyrwan OD** in elderly patients with dementia is not recommended as it may have serious side effects.

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

- Diabetes
- Heart disease
- Liver or kidney disease
- Parkinson's disease
- Epilepsy
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Blood disorders
- Stroke or temporary symptoms of stroke

If you suffer from dementia, you or your carer/relative should tell your doctor if you have ever had a stroke or temporary symptoms of stroke.

As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor. **Zyrwan OD** is not for patients who are under 18 years.

Taking other medicines

Only take other medicines while you are on **Zyrwan OD** if your doctor tells you that you can. You might feel drowsy if **Zyrwan OD** is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

You should tell your doctor if you are taking fluvoxamine (an antidepressant), or ciprofloxacin (an antibiotic), as it may be necessary to change your **Zyrwan OD** dose.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially tell your doctor if you are taking medicines for Parkinson's disease.

Taking Zyrwan OD with food and drink

Do not drink any alcohol if you have been given **Zyrwan OD** as **Zyrwan OD** and alcohol together may make you feel drowsy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor as soon as possible if you are pregnant or think you may be pregnant. You should not take this medicine when pregnant, unless you have discussed this with your doctor. You should not be given this medicine when breast-feeding, as small amounts of olanzapine can pass into breast milk.

Driving and using machines

There is a risk of feeling drowsy when you are given **Zyrwan OD**. If this happens do not drive or operate any tools or machines. Tell your doctor.

Important information about some of the ingredients of Zyrwan OD

It should be known that **Zyrwan OD** contains aspartame, a source of phenylalanine, and may be harmful for people with phenylketonuria.

Patients who cannot take mannitol should note that **Zyrwan OD** contains mannitol, which may have a mild laxative effect.

3. How to take Zyrwan OD

Always take **Zyrwan OD** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

You should take your **Zyrwan OD** 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. **Zyrwan OD** orodispersible tablets are for oral use.

Zyrwan OD 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 colour and possibly become cloudy. Drink it straight away.

If you take more Zyrwan OD than you should

Patients who have taken more **Zyrwan OD** than they should, have experienced the following symptoms: rapid beating of the heart, 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 or hospital straight away. Show the doctor your pack of tablets.

If you forget to take Zyrwan OD

Do not take a double dose to make up for a forgotten dose. Take your tablets as soon as you remember. Do not take two doses in one day.

If you stop taking Zyrwan OD

Do not stop taking your tablets just because you feel better. It is important that you carry on taking **Zyrwan OD** for as long as your doctor tells you.

If you suddenly stop taking **Zyrwan OD**, 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **Zyrwan OD** can cause side effects, although not everybody gets them.

Very common side effects: affect 1 patient in 10

- Weight gain.
- Sleepiness.
- Increases in the levels of prolactin in the blood.

Common side effects: affect 1 to 10 patients in 100

- Changes in the levels of some blood cells and circulating fats.
- Increases in the level of sugars in the blood and urine.
- Feeling more hungry.
- Dizziness.
- Restlessness.
- Tremor.
- Muscle stiffness or spasm (including eye movements).
- Problems with speech.
- Unusual movement (especially of the face or tongue).
- Constipation.
- Dry mouth.
- Rash.
- Loss of strength.
- Extreme tiredness.
- Water retention leading to swelling of the hands, ankles or feet.
- 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.
- Sexual dysfunction such as decreased libido in males and females or erectile dysfunction in males.

Uncommon side effects: affect 1 to 10 patients in 1000

- Slow heart rate.
 - Make you sensitive to sunlight.
 - Hair loss.
 - Absence or decrease in menstrual periods.
- Rare side effects: affect 1 to 10 patients in 10,000
- Male or female breast enlargement.
- Other possible side effects: frequency cannot be estimated from the available data.
- Allergic reaction (e.g. swelling in the mouth and throat, itching, rash).
 - Diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma.
 - Lowering of normal body temperature.
 - Seizures, usually associated with a history of seizures (epilepsy).
 - Combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness.
 - Spasms of the muscle of the eye causing rolling movement of the eye.
 - Abnormal rhythms of the heart.
 - Sudden unexplained death.
 - Blood clots such as deep venous thrombosis of the leg or blood clot on the lung.
 - 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.
 - Difficulty in passing urine.
 - Prolonged and/or painful erection.

While taking olanzapine, 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 **Zyrwan OD** may worsen the symptoms.

Rarely women taking medicines of this type for a long time have started to secrete milk and have missed periods or had irregular periods. If this persists tell your doctor. Very rarely babies born to mothers who have taken **Zyrwan OD** in the last stage of pregnancy (3rd trimester) may have tremors, be sleepy or drowsy.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Zyrwan OD

Keep out of the reach and sight of children.

Do not use **Zyrwan OD** after the expiry date which is stated on the carton.

Store below 25°C. Protect from light.

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.

6. Further information

What Zyrwan OD contains

The active substance is olanzapine. Each **Zyrwan OD** orodispersible tablet contains either 5 mg, 10 mg, 15 mg or 20 mg of the active substance. The exact amount is shown on your **Zyrwan OD** pack. The other ingredients are: mannitol (E421), crospovidone, aspartame (E951), orange flavor, colloidal anhydrous silica and sodium stearyl fumarate.

What Zyrwan OD looks like and contents of the pack

Zyrwan OD 5 mg, 10 mg, 15 mg and 20 mg are presented as yellow orodispersible tablets, engraving on one side "5", "10", "15" and "20" respectively.

Orodispersible tablet is the technical name given to a tablet that dissolves directly in the mouth, hence could be easily swallowed.

Zyrwan OD 5 mg, 10 mg, 15 mg and 20 mg are available in packs of 14 or 28 tablets.

Manufactured by: Zakład Farmaceutyczny Adamed Pharma S.A.

Ksawerów, Poland

For: ARWAN Pharmaceutical Industries Lebanon s.a.l.

Jadra, Lebanon

THIS IS A MEDICAMENT

- 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 medicines, their 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.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists