

SCHEDULING STATUS S5

ZYPREXA VELOTAB 5 mg (orodispersible tablets)

ZYPREXA VELOTAB 10 mg (orodispersible tablets)

Olanzapine

Contains sugar: 4,50 mg and 6,00 mg mannitol per orodispersible tablet, respectively.

Contains sweetener: 0,60 mg and 0,80 mg aspartame per orodispersible tablet, respectively.

Read all of this leaflet carefully before you start taking ZYPREXA VELOTAB.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZYPREXA VELOTAB has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ZYPREXA VELOTAB is and what it is used for

ZYPREXA VELOTAB contains the active substance olanzapine. ZYPREXA VELOTAB belongs to a group of medicines called antipsychotics.

ZYPREXA VELOTAB is used to treat the following conditions:

- The management of **psychotic disorders, such as 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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 acute manic episode**, a condition with symptoms of excitement or euphoria.
- **Prevention of recurrence of manic or depressive episodes in patients with bipolar disorder.**

2. What you need to know before you take ZYPREXA VELOTAB

Do not take ZYPREXA VELOTAB:

- If you are allergic (hypersensitive) to olanzapine or any of the ingredients of ZYPREXA VELOTAB (listed in section 6). 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 of the eye).

Warnings and precautions

Take special care with ZYPREXA VELOTAB:

- The use of ZYPREXA VELOTAB in elderly patients with dementia is not recommended as it may have serious side effects.
- ZYPREXA VELOTAB may cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.
- ZYPREXA VELOTAB may cause unusual movements mainly of the face or tongue. If this happens after you have been given ZYPREXA VELOTAB, tell your doctor.
- Weight gain has been seen in patients taking ZYPREXA VELOTAB. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.
- ZYPREXA VELOTAB may cause high blood sugar levels. Your doctor should do blood tests to check blood sugar before you start taking ZYPREXA VELOTAB and regularly during treatment.
- ZYPREXA VELOTAB may cause elevations of liver enzymes if you suffer from a liver disease or if you are

treated with medicines that can potentially damage the liver.

- ZYPREXA VELOTAB may cause dysphagia (swallowing difficulties). Tell your doctor if you are at risk for aspiration pneumonia (lung infection due to the inhalation of stomach content and/or secretion of oropharynx).
- Tell the doctor if you or someone else in your family has a history of blood clots, as ZYPREXA VELOTAB 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)
 - Prostate problems
 - A blocked intestine (paralytic ileus)
 - Increased pressure in the eye (glaucoma)
 - Liver disease
 - Blood disorders
 - Heart disease
 - Diabetes
 - Seizures
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- If you suffer from dementia, you or your carer/relative should tell your doctor if you have ever had a stroke or “mini” stroke.
 - As a routine precaution, if you are over 65 years your blood pressure should be monitored regularly by your doctor.

Inform your doctor if you are a smoker; smoking will affect your dosing of ZYPREXA VELOTAB.

Other medicines and ZYPREXA VELOTAB

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Only take other medicines while you are on ZYPREXA VELOTAB if your doctor tells you that you can.

You might feel drowsy if ZYPREXA VELOTAB is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquilisers).

In particular, tell your doctor if you are taking:

- activated charcoal
- 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 ZYPREXA VELOTAB dose.

Taking ZYPREXA VELOTAB with food and drink

- You can take ZYPREXA VELOTAB with or without food.
- Do not drink any alcohol if you have been given ZYPREXA as together with alcohol it may make you feel drowsy.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Usage in pregnancy:

The safety of ZYPREXA VELOTAB in pregnancy has not been established.

The following symptoms may occur in newborn babies, of mothers that have used ZYPREXA VELOTAB 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.

Usage during breastfeeding:

The safety of ZYPREXA VELOTAB has not been established in breastfeeding women. ZYPREXA VELOTAB is not recommended in breastfeeding mothers.

Driving and using machines

There is a risk of feeling drowsy after you have taken ZYPREXA VELOTAB. If this happens do not drive or operate any tools or machines. Tell your doctor.

It is not always possible to predict to what extent ZYPREXA VELOTAB may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ZYPREXA VELOTAB affects you.

ZYPREXA VELOTAB contains aspartame, sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate

This medicine contains up to 1,6 mg aspartame in each tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine build up because the body cannot remove it properly.

This medicine contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed). An allergic reaction may be recognised as a rash, itching or shortness of breath. This may occur immediately or some time after you take ZYPREXA VELOTAB.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take ZYPREXA VELOTAB

Do not share medicines prescribed for you with any other person.

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

Your doctor will tell you how long your treatment with ZYPREXA VELOTAB will last. Do not stop treatment early

because you may get “withdrawal symptoms” such as diarrhoea, feeling sick, vomiting, feeling anxious, having trouble sleeping and shaking. If you have the impression that the effect of ZYPREXA VELOTAB is too strong or too weak, tell your doctor or pharmacist.

The daily dose of ZYPREXA VELOTAB is between 5 mg and 20 mg.

Consult your doctor if your symptoms return but do not stop taking ZYPREXA VELOTAB unless your doctor tells you to.

You should take your ZYPREXA VELOTAB tablet 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. ZYPREXA VELOTAB orodispersible tablets are for oral use.

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

1. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing.
3. Gently push the tablet out.
4. 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.

Safety and efficacy of ZYPREXA VELOTAB in children below 18 years of age have not been established.

If you take more ZYPREXA VELOTAB than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or

poison centre.

Symptoms of overdose include 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 if you experience any of the above symptoms. Show the doctor your pack of tablets.

If you forget to take ZYPREXA VELOTAB

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

If you stop taking ZYPREXA VELOTAB

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

If you suddenly stop taking ZYPREXA VELOTAB, symptoms such as sweating, inability to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you 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

ZYPREXA VELOTAB can have side effects.

Not all side effects reported for ZYPREXA VELOTAB are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZYPREXA VELOTAB, please consult your

healthcare provider for advice.

If any of the following happens, stop taking ZYPREXA VELOTAB and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

These are all very serious side effects. If you have them, you may have had a serious reaction to ZYPREXA VELOTAB. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you have:

- unusual movement (a frequent side effect) mainly of the face or tongue;
- blood clots in the veins (less frequent side effect) 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 (frequency cannot be estimated).

Frequent side effects:

- loss of strength;
- weight gain;
- extreme tiredness;
- some people may feel dizzy or faint (with a slow heart rate), especially when getting up from lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.
- constipation;
- dry mouth;
- feeling more hungry;

- increases or decreases of level of certain types of white blood cells;
- water retention leading to swelling of the hands, ankles or feet;
- restlessness;
- dizziness;
- sleepiness;
- increases in liver enzymes;
- increases of level of prolactin in the blood;
- involuntary leakage of urine;
- lung infection (pneumonia);
- falls;
- abnormal gait – walking unsteady, shuffling or dragging feet;
- hallucinations (seeing and hearing things not real);
- symptoms of Parkinson's disease such as tremor, slowed movement, rigidity, impaired balance and posture;
- trembling or shakiness;
- difficulty speaking.

Less frequent side effects:

- lower than normal white blood cells
- decreases of level of blood platelets;
- seizures;
- slow heart rate;
- inflammation of the pancreas causing severe stomach pain, fever and sickness;
- liver inflammation;
- sensitivity to sunlight;
- rash;
- muscle disease presenting as unexplained aches and pains;
- prolonged and/or painful erection.

Side effects with unknown frequency

- life-threatening unconscious state caused by dangerously high or low blood sugar levels in people with diabetes;
- an excess of fat in the bloodstream;
- an excess of glucose in the bloodstream;
- blood clot in a vein.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZYPREXA VELOTAB.

5. How to store ZYPREXA VELOTAB

Store all medicines out of reach of children.

Store at or below 30 °C in the original container.

Protect from light and moisture.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZYPREXA VELOTAB contains

- ZYPREXA VELOTAB orodispersible tablets contain the active substance olanzapine 5 mg, or 10 mg respectively.

- The other ingredients are aspartame (E951), gelatin, mannitol (E421), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydrobenzoate (E217).

What ZYPREXA VELOTAB looks like and contents of the pack

Yellow, round, freeze dried, rapid-dispersing orodispersible tablets to be placed in the mouth or alternatively to be dispersed in water or other suitable beverage for administration.

ZYPREXA VELOTAB orodispersible tablets are supplied in blister strips of 28. The blisters consist of aluminium-plastic web film sealed with an aluminium foil lid.

Holder of Certificate of Registration

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This leaflet was last revised in

21 July 2026

Registration numbers

ZYPREXA VELOTAB 5 mg: 38/2.6.5/0030

ZYPREXA VELOTAB 10 mg: 38/2.6.5/0073