Package leaflet: Information for the user

ZYPREXA VELOTAB 5 mg orodispersible tablets
ZYPREXA VELOTAB 10 mg orodispersible tablets
ZYPREXA VELOTAB 15 mg orodispersible tablets
ZYPREXA VELOTAB 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. See section 4.

What is in this leaflet

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 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.

ZYPREXA VELOTAB 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 ZYPREXA VELOTAB

Do not take ZYPREXA VELOTAB
- 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 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)**.**

Warnings and precautions
Talk to your doctor or pharmacist before you take ZYPREXA VELOTAB
- The use of ZYPREXA VELOTAB 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 ZYPREXA VELOTAB 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.
- 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.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking ZYPREXA VELOTAB. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking ZYPREXA VELOTAB 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 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 may be monitored by your doctor.

Children and adolescents
ZYPREXA VELOTAB is not for patients who are under 18 years.

Other medicines and ZYPREXA VELOTAB
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 (tranquillisers).

Tell your doctor if you are taking, have recently taken or might take any other medicines

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 ZYPREXA VELOTAB dose.

ZYPREXA VELOTAB with alcohol
Do not drink any alcohol if you have been given ZYPREXA VELOTAB 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 ZYPREXA VELOTAB can pass into breast milk.

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.

Driving and using machines
There is a risk of feeling drowsy when you are given ZYPREXA VELOTAB. If this happens do not drive or operate any tools or machines. Tell your doctor.

ZYPREXA VELOTAB contains aspartame, mannitol and sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate
Patients who cannot take phenylalanine should note that ZYPREXA VELOTAB contains aspartame, which is a source of phenylalanine. May be harmful for people with phenylketonuria.

Patients who cannot take mannitol should note that ZYPREXA VELOTAB contains mannitol.

ZYPREXA VELOTAB contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate, which may cause an allergic reaction in some people. 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.

3. How to take ZYPREXA VELOTAB

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 ZYPREXA VELOTAB tablets to take and how long you should continue to take them. 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 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. 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.

If you take more ZYPREXA VELOTAB than you should
Patients who have taken more ZYPREXA VELOTAB 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 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 two doses in one day.

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, 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 the 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); problems with speech; 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 (may affect up to 1 in 1000 people) include 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.

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 ZYPREXA VELOTAB may worsen the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ZYPREXA VELOTAB

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton**.**

ZYPREXA VELOTAB should be stored in its original pack in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What ZYPREXA VELOTAB contains

- The active substance is olanzapine. Each ZYPREXA VELOTAB orodispersible tablet contains either 5 mg, 10 mg, 15 mg or 20 mg of the active substance. The exact amount is shown on your ZYPREXA VELOTAB pack.
- The other ingredients are
  - gelatin, mannitol (E421), aspartame (E951), sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217).

What ZYPREXA VELOTAB looks like and contents of the pack

ZYPREXA VELOTAB 5 mg, 10 mg, 15 mg and 20 mg 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.

ZYPREXA VELOTAB is available in packs containing 28, 35, 56, 70 or 98 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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