

Vaincor® 5 mg, Film-coated scored tablets Vaincor® 10 mg, Film-coated scored 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 VAINCOR is and what it is used for ?
2. What you need to know before you take VAINCOR ?
3. How to take VAINCOR ?
4. Possible side effects ?
5. How to store VAINCOR ?
6. Contents of the pack and other information

1. What VAINCOR is and what it is used for ?

- Treatment of schizophrenia: in patients who initially responded to treatment, olanzapine has proved its efficiency to maintain this improvement in the long term.
- Olanzapine is indicated in the treatment of moderate to severe manic episodes
- Olanzapine is indicated in the prevention of recurrences in patients presenting a bipolar disorder who already responded to treatment with Olanzapine during a manic episode.

2. What you need to know before you take VAINCOR ?

Do not take VAINCOR

- 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 VAINCOR.

- The use of VAINCOR 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 VAINCOR 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 VAINCOR. 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 VAINCOR. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking VAINCOR 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 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

VAINCOR is not for patients who are under 18 years.

Other medicines and VAINCOR

Only take other medicines while you are on VAINCOR if your doctor tells you that you can. You might feel drowsy if VAINCOR 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 VAINCOR dose.

VAINCOR with alcohol

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

The following symptoms may occur in newborn babies, of mothers that have used VAINCOR 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 VAINCOR. If this happens do not drive or operate any tools or machines. Tell your doctor.

VAINCOR contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take VAINCOR ?

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

You should take your VAINCOR 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. VAINCOR tablets are for oral use. You should swallow the VAINCOR tablets whole with water.

If you take more VAINCOR than you should

Patients who have taken more VAINCOR 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 VAINCOR

Take your tablets as soon as you remember. Do not take two doses in one day.

If you stop taking VAINCOR

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

If you suddenly stop taking VAINCOR, 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); 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 (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.

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

5. How to store VAINCOR ?

To store at a temperature between 15° C and 30° C

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.

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 VAINCOR contains

- The active substance is olanzapine. Each tablet contains either, 5 mg or 10 mg, of the active substance.
- The other ingredients are

-Tablet core: lactose monohydrate, microcrystalline cellulose, carmellose sodium, magnesium stearate tablet coating: Opadry II white (for VAINCOR 5mg), Opadry II Orange (for VAINCOR 10mg)

What VAINCOR looks like and contents of the pack

VAINCOR is a film-coated scored tablet in blister ALU/ALU.

VAINCOR is available in Box of 28 and 91 tablets.

Conditions of prescription and dispensing: List I

M.A.N.:

VAINCOR 5mg, Box of 28: 9233451

VAINCOR 5mg, Box of 91: 9233454

VAINCOR 10mg, Box of 28: 9233453

VAINCOR 10mg, Box of 91: 9233455

Marketing Authorisation Holder and Manufacturer

LES LABORATOIRES MEDIS - S.A.

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This is a Medicament

- A medicine is a product but not like any others product.
- A medicine is a product that affects your health. If it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of your Doctor and the use instructions prescribed.
- follow your pharmacist advice.
- Your doctor and your pharmacist know the medicine, its use and side effect.
- Do not stop the use of the treatment on your own during the prescribed time.
- Don't retake, don't increase the doses without doctor's advice

Keep all medicaments out of reach of children