

PACKAGE LEAFLET: INFORMATION FOR THE USER

OLENXA[®] 5 mg orodispersible tablets
OLENXA[®] 10 mg orodispersible tablets
OLENXA[®] 15 mg orodispersible tablets
OLENXA[®] 20 mg orodispersible tablets
Olanzapine

Read all of this 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 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 you get any side effects, please talk to your doctor, or pharmacist or other healthcare professional or directly to the National Medicines Agency (Mesogion 284, 15562, Cholargos, www.eof.gr)

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1. WHAT OLENXA[®] ARE AND WHAT THEY ARE USED FOR

Olenxa[®] belong to a group of medicines called antipsychotics.

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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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

Olenxa[®] 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 OLENXA[®]**Do not take Olenxa[®] if you**

- are allergic (hypersensitive) to olanzapine or other ingredients of **Olenxa[®]**. 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.
- have been previously diagnosed with eye problems such as certain kinds of glaucoma- angle closure glaucoma (increased pressure in the eye).

Take special care with Olenxa[®]

- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given **Olenxa[®]**, 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 **Olenxa[®]** 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 "mini" stroke (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 "mini" stroke.

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

Olenxa[®] are not for patients who are under 18 years.

Taking other medicines

Only take other medicines while you are on **Olenxa**[®] if your doctor tells you that you can. You might feel drowsy if **Olenxa**[®] 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 **Olenxa**[®] 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 Olanzapine tablets with food and drink

Do not drink any alcohol if you have been given **Olenxa**[®] as **Olenxa**[®] and alcohol together may make you feel drowsy.

Pregnancy and breast-feeding

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 breastfeeding, as small amounts of **Olenxa**[®] can pass into breast milk.

Driving and using machines

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

Important information about some of the ingredients of Olenxa[®]

Patients who cannot take phenylalanine should note that **Olenxa**[®] contains aspartame, which is a source of phenylalanine. May be harmful for people with phenylketonuria.

3. HOW TO TAKE OLENXA[®]

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

You should take **Olenxa**[®] 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. **Olenxa**[®] is for oral use.

Olenxa[®] 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 Olenxa[®] than you should

Patients who have taken more **Olenxa**[®] 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 Olenxa[®]

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

If you stop taking Olenxa[®]

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

If you suddenly stop taking **Olenxa**[®], 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, **Olenxa**[®] can cause side effects, although not everybody gets them.

Very common side effects: affect 1 user in 10

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

Common side effects: affect 1 to 10 users in 100

- Changes in the levels of some blood cells and circulating fats
- Increases in the levels 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 dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Uncommon side effects: affect 1 to 10 users in 1,000

- Slow heart rate
- Make you sensitive to sunlight
- Urinary incontinence
- Hair loss
- Absence or decrease in menstrual periods
- Changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth

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 in the vein
- 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 **Olenxa**[®] 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 Olanzapine in the last stage of pregnancy (3rd trimester) may have tremors, be sleepy or drowsy.

If you get any side effects, please talk to your doctor, or pharmacist or other healthcare professional or directly to the National Medicines Agency (Mesogion 284, 15562, Cholargos, www.eof.gr)

5. HOW TO STORE OLENXA®

Keep out of the reach and sight of children.

Do not use **Olenxa**® after the expiry date, which is stated on the carton.

Store **Olenxa**® in the original package in order to protect from light and moisture.

Please return left over medicine to your pharmacist. 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 Olenxa® contains

- The active substance is olanzapine. Each orodispersible tablet contains either 5 mg, 10 mg, 15 mg, ή 20 mg of the active substance. The exact amount is shown on your **Olenxa**® pack.
- The other ingredients are: magnesium stearate, L-Methionine, silica colloidal anhydrous, hydroxypropyl cellulose, crospovidone, aspartame, microcrystalline cellulose, guar gum, magnesium carbonate heavy and orange flavour.

What Olenxa® look like and contents of the pack

Olenxa® 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.

Olenxa® 5 mg, 10 mg, 15 mg and 20 mg are available in packs containing 28 tablets. Not all pack sizes may be marketed.

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For any information about this medicine, please contact the the Marketing Authorisation Holder