CP.OLZ.JNT.EP.V3P1

Package leaflet: Information for the user

OLANZAPINE 2.5mg, 5mg, 10mg, 15mg AND 20mg FILM-COATED TABLETS

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.**

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1. WHAT OLANZAPINE FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Olanzapine Film-coated Tablets belong to a group of medicines called antipsychotics and are 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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

Olanzapine 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 OLANZAPINE FILM-COATED TABLETS

Do not take Olanzapine Film-coated Tablets:
- 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 Olanzapine Film-coated Tablets.
- The use of Olanzapine Film-coated Tablets 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 Olanzapine Film-coated Tablets 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 Olanzapine Film-coated Tablets. 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 Olanzapine Film-coated Tablets. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Olanzapine Film-coated Tablets 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)

See also section 4, “Possible side effects”.

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
Olanzapine Film-coated Tablets are not suitable for patients who are under 18 years.

Other medicines and Olanzapine Film-coated Tablets
Only take other medicines while you are on Olanzapine Film-coated Tablets if your doctor tells you that you can. You might feel drowsy if Olanzapine Film-coated Tablets are taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquilisers).

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 Olanzapine dose

Olanzapine Film-coated Tablets with alcohol
Do not drink any alcohol if you have been given Olanzapine Film-coated Tablets as Olanzapine and alcohol together 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 Olanzapine Film-coated Tablets can pass into breast milk.

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

Olanzapine Film-coated Tablets contain 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 OLANZAPINE FILM-COATED TABLETS

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

You should take your Olanzapine Film-coated 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.
Olanzapine Film-coated Tablets are for oral use. You should swallow the Olanzapine Film-coated Tablets whole with water.

If you take more Olanzapine Film-coated Tablets than you should
Patients who have taken more Olanzapine Film-coated Tablets 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 Olanzapine Film-coated Tablets
Take your tablets as soon as you remember. Do not take two doses in one day.

If you stop taking Olanzapine Film-coated Tablets
Do not stop taking your tablets just because you feel better. It is important that you carry on taking Olanzapine Film-coated Tablets for as long as your doctor tells you.

If you suddenly stop taking Olanzapine Film-coated Tablets, 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 experience any of these symptoms:
- 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)

Tell your doctor if any of the below side effects start bothering you.

Very common side effects (may affect more than 1 in 10 people) include:
- weight gain
- sleepiness
- increases in the 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 and 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 dysfunction 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
- slow heart rate
- stuttering
- sensitivity to sunlight
- bleeding from the nose
- abdominal distension
- drooling
- memory loss or forgetfulness
- urinary incontinence; lack of ability to urinate
- hair loss
- absence or decrease in menstrual periods
- changes in breasts in males and females such as 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
- 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 in blood tests and an increase in a type of white blood cell (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 Olanzapine Film-coated Tablets may worsen the symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellowcard in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE OLANZAPINE FILM-COATED TABLETS

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not use this medicine after the expiry date, which is stated on the blister and carton. The expiry date refers to the last day of that month.
Store below 25°C.
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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Olanzapine Film-coated Tablets contain
- The active substance is olanzapine. Each Olanzapine Film-coated Tablet contains either 2.5mg, 5mg, 10mg, 15mg or 20mg of the active substance. The exact amount is shown on your Olanzapine tablet pack.
- The other ingredients are (tablet core) lactose monohydrate, hyprolose (E463), crospovidone (E1202), microcrystalline cellulose (E460), magnesium stearate (E572) and (tablet coating) polyvinyl alcohol, talc (E553b), titanium dioxide (E171), lactose monohydrate and triacetin.

What Olanzapine Film-coated Tablets look like and contents of the pack
Olanzapine 2.5mg Film-coated Tablets are off-white to pale yellow and debossed with “2.5” on one side and blank on the other.
Olanzapine 5mg Film-coated Tablets are off-white to pale yellow and debossed with “5” on one side and blank on the other.
Olanzapine 10mg Film-coated Tablets are off-white to pale yellow and debossed with “10” on one side and blank on the other.
Olanzapine 15mg Film-coated Tablets are off-white to pale yellow and debossed with “15” on one side and blank on the other.
Olanzapine 20mg Film-coated Tablets are off-white to pale yellow and debossed with “20” on one side and blank on the other.

Olanzapine 2.5mg, 5mg, 10mg and 15mg Film-coated Tablets are available in 28, 50, 56, 60 and 70 tablet packs.
Olanzapine 20mg Film-coated Tablets are available in 28 tablet packs.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer
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Customer: Athlone **Designer:** ABC (AWG)
Product: Olanzapine Film-coated Tablets
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Proof No and Date: 1 16/10/2022
Revision: Removal of Ashford as BR site
ARTWORK FOR SUBMISSION
Supersedes: V2P1

Colours
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Kent Pharma Logo
CMYK