

PACKAGE LEAFLET: INFORMATION FOR THE USER

Olanzapine Clonmel 5mg Orodispersible Tablets Olanzapine Clonmel 10mg Orodispersible Tablets Olanzapine Clonmel 15mg Orodispersible Tablets Olanzapine Clonmel 20mg 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, pharmacist or nurse.
- 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, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. WHAT OLANZAPINE CLONMEL IS AND WHAT IT IS USED FOR

Olanzapine Clonmel contains the active substance olanzapine. Olanzapine Clonmel 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.

Olanzapine Clonmel 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 CLONMEL

Do not take Olanzapine Clonmel

- if you are allergic (hypersensitive) to olanzapine or any of the other ingredients of Olanzapine Clonmel. 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, pharmacist or nurse before taking Olanzapine Clonmel

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

Olanzapine Clonmel is not for patients who are under 18 years.

Other medicines and Olanzapine Clonmel

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

Olanzapine Clonmel with alcohol

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

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

Olanzapine Clonmel contains aspartame

Contains a source of phenylalanine. May be harmful for people with phenylketonuria.

3. HOW TO TAKE OLANZAPINE CLONMEL

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

You should take your Olanzapine Clonmel 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 Clonmel orodispersible tablets are for oral use.

Olanzapine Clonmel 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 Olanzapine Clonmel than you should

Patients who have taken more Olanzapine Clonmel 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 Clonmel

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

If you stop taking Olanzapine Clonmel

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

If you suddenly stop taking Olanzapine Clonmel, 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, Olanzapine Clonmel 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)
- serious allergic reactions, e.g. swelling in the mouth and throat, itching, rash (an uncommon side effect that may affect up to 1 in 100 people)
- prolonged and/or painful erection (a rare side effect that may affect up to 1 in 1,000 people)
- inflammation of the pancreas causing severe stomach pain, fever and sickness (a rare side effect that may affect up to 1 in 1,000 people)
- muscle disease e.g. rhabdomyolysis, presenting as unexplained aches and pains (a rare side effect that may affect up to 1 in 1,000 people)
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes (jaundice), and dark coloured urine (a rare side effect that may affect up to 1 in 1,000 people).

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).

Very common side effects (may affect more than 1 in 10 people) include

- Weight gain.
- Sleepiness.
- 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 and circulating fats and early in treatment, temporary increases in liver enzymes.
- Increases in the levels 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.
- 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

- 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.
- 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.

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 Clonmel may worsen the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OLANZAPINE CLONMEL

Keep this medicine out of the sight and reach of children.

Do not use Olanzapine Clonmel after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Store in the original package 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 Olanzapine Clonmel contains

- The active substance is olanzapine. Each Olanzapine Clonmel orodispersible tablet contains either 5 mg, 10 mg, 15 mg or 20 mg of the active substance. The exact amount is shown on your Olanzapine Clonmel pack.
- The other ingredients are magnesium stearate, L-Methionine, silica colloidal anhydrous, hydroxypropyl cellulose (low substituted), crospovidone (Type B), aspartame (E951), microcrystalline cellulose, guar gum, magnesium carbonate heavy and orange flavour.

What Olanzapine Clonmel looks like and contents of the pack

Olanzapine Clonmel 5 mg orodispersible tablet is a round, biconvex, yellow tablet, 6 mm in diameter and marked with "O" on one side.

Olanzapine Clonmel 10 mg orodispersible tablet is a round biconvex, yellow tablet 8 mm in diameter and marked with "O1" on one side.

Olanzapine Clonmel 15 mg orodispersible tablet is a round, biconvex, yellow tablet, 9 mm in diameter and marked with "O2" on one side.

Olanzapine Clonmel 20 mg orodispersible tablet is a round, biconvex, yellow tablet, 10 mm in diameter and marked with “O3” on one side.

Pack sizes:

Push-through blister packs: 10 (sample), 14, 28, 30, 56, 60, 98, 126 and 154 orodispersible tablets.

Peel-to open blister packs: 10 (sample), 14, 28, 30, 56, 60, 98, 126 and 154 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Actavis hf, Reykjavíkurvegi 78, IS-220 Hafnarfjörður, Iceland

Actavis Ltd, B16 Bulebel Industrial Estate, Zejtun ZTN 08, Malta

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Olanzapin STADA 5mg, 10mg, 15 mg Schmelztabletten
Belgium	Olanzapine Instant EG 5 mg, 10 mg orodispergeerbare tabletten
Czech Republic	Olanzapin STADA OROTAB 5 mg, 10 mg
Hungary	Olanzapin STADA 5 mg, 10 mg szájban diszpergálódó tabletta
Ireland	Olanzapine Clonmel 5mg, 10mg, 15mg, 20mg orodispersible tablets
Italy	OLANZAPINA EUROGENERICI 5 mg, 10 mg compresse orodispersibili
Luxembourg	Olanzapine Instant EG 5 mg, 10 mg comprimés orodispersibles
Portugal	Olanzapina Ciclum
Spain	Olanzapina Flas STADA 5 mg, 10 mg comprimidos bucodispersables EFG
Slovak Republic	Olanzapin STADA 5 mg, 10 mg
Sweden	Olanzapine STADA 5 mg, 10mg, 15mg, 20mg munsönderfallande tabletter
United Kingdom	Olanzapine Excalibur 5 mg, 10mg, 15mg, 20mg Orodispersible Tablets

This leaflet was last approved in July 2016.