

Package leaflet: information for the user

**Kozylex 5 mg,
Kozylex 10mg,
Kozylex 15mg,
Kozylex 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 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 Kozylex is and what it is used for
2. What you need to know before you take Kozylex
3. How to take Kozylex
4. Possible side effects
5. How to store Kozylex
6. Contents of the pack and other information

1. What Kozylex is and what it is used for

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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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

Kozylex 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 Kozylex

Do not take Kozylex

- If you are allergic 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 Kozylex

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

Kozylex is not for patients who are under 18 years.

Other medicines and Kozylex

Only take other medicines while you are on Kozylex if your doctor tells you that you can. You might feel drowsy if Kozylex is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

Tell your doctor or pharmacist 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), as it may be necessary to change your Kozylex dose.

Kozylex with alcohol

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

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

Kozylex 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 Kozylex

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

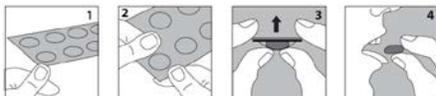
Your doctor will tell you how many Kozylex tablets to take and how long you should continue to take them. The daily dose of Kozylex is between 5 and 20 mg. Consult your doctor if your symptoms return but do not stop taking Kozylex unless your doctor tells you to.

You should take your Kozylex 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. Kozylex orodispersible tablets are for oral use.

Kozylex 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 & 2. Hold the blister strip at the edges.
3. Gently push the tablet out to avoid breaking.
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 Kozylex than you should

Patients who have taken more Kozylex 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 Kozylex

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

If you stop taking Kozylex

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

If you suddenly stop taking Kozylex, 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, 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: may affect more than 1 in 10 people

- 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: may affect up to 1 in 10 people

- 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
- Sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males

Uncommon: may affect up to 1 in 100 people

- 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
- Hair loss.
- Urinary incontinence
- Lack of ability to urinate
- 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 (may affect up to 1 in 1000 people)

- 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.

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 Kozylex 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 Kozylex

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 and blister after EXP. The expiry date refers to the last day of the month.

Store in the 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 Kozylex contains

- The active substance is olanzapine. Each Kozylex orodispersible tablet contains 5 mg, 10mg, 15mg or 20mg of the active substance.
- The other ingredients are crospovidone (type A), lactose monohydrate, colloidal silicon dioxide (anhydrous), hydroxypropylcellulose, mint flavour (consisting of: mint oil, terpeneless mint oil, eucalyptol, menthone, isomenthone, methylene acetate, menthol), talc, magnesium stearate

What Kozylex looks like and contents of the pack

Kozylex 5 mg, 10mg, 15mg and 20mg 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.

Kozylex 5 mg, 10mg, 15mg and 20mg are available in cartons containing:

10, 28, 30, 35, 56, 60 and 70 orodispersible tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

IWA Consulting Aps
Ølby Center 7,1
4600 KØge
Denmark

Manufacturer

Pharmathen S.A.
Dervenakion 6
15351 Pallini
Attiki
Greece

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

Denmark	Kozylex
Austria	Olanzapine G.L. 5 mg, 10mg, 15 mg Schmelztabletten

Ireland
Iceland

Kozylex
Kozylex

This leaflet was last revised in 02/2015