


Rolyprex® 2.5 mg Film-Coated Tablets
Rolyprex® 5 mg Film-Coated Tablets
Rolyprex® 7.5 mg Film-Coated Tablets
Rolyprex® 10 mg Film-Coated Tablets
Rolyprex® 15 mg Film-Coated 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 Rolyprex® is and what it is used for
2. What you need to know before you take Rolyprex®
3. How to take Rolyprex®
4. Possible side effects
5. How to store Rolyprex®
6. Contents of the pack and other information



1 What Rolyprex® is and what it is used for

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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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

Rolyprex® 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 Rolyprex®

Do not take Rolyprex®

- 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 Rolyprex®.

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

Rolyprex® is not for patients who are under 18 years.

Other medicines and Rolyprex®

Only take other medicines while you are on Rolyprex® if your doctor tells you that you can. You might feel drowsy if Rolyprex® 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) - it may be necessary to change your Rolyprex® dose.

Rolyprex® with alcohol

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

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

Rolyprex® 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 Rolyprex®

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 Rolyprex® tablets to take and how long you should continue to take them. The daily dose of Rolyprex® is between 5 mg and 20 mg.

Consult your doctor if your symptoms return but do not stop taking Rolyprex® unless your doctor tells you to.

You should take your Rolyprex® 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. Rolyprex® film-coated tablets are for oral use. You should swallow the Rolyprex® tablets with water.

If you take more Rolyprex® than you should

Patients who have taken more Rolyprex® 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 Rolyprex®

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

If you stop taking Rolyprex®

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

If you suddenly stop taking Rolyprex®, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you 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 (a rare side effect that may affect up to 1 in 1,000 people).

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.

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Common side effects (may affect up to 1 in 10 people) include:

- Changes in the levels of some blood cells and circulating fats
- Temporary increases in liver enzymes, especially early in treatment
- 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 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
- 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 1,000 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 Rolyprexa 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 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 Rolyprexa

Keep Rolyprexa out of the sight and reach of children.

Do not use Rolyprexa after the expiry date which is stated on the carton and on the blister/label of the HDPE-bottle. The expiry date refers to the last day of that month.

Blister/HDPE bottles before first opening: This medicinal product does not require any special storage conditions.

HDPE bottle after first opening: Do not use Rolyprexa after 6 months have elapsed from opening of the HDPE-bottle. Do not store above 25°C.

Do not throw away Rolyprexa via wastewater or household waste. Ask your pharmacist how to throw away Rolyprexa you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Rolyprexa contains
The active substance is olanzapine.
Each film-coated tablet contains either 2.5 mg, 5 mg, 7.5 mg, 10 mg or 15 mg of olanzapine.

The other ingredients are
Tablet core: lactose monohydrate, hydroxypropylcellulose, crospovidone, microcrystalline cellulose, magnesium stearate.
Tablet coat: polyvinyl alcohol, macrogol 3350, titanium dioxide (E171), talc.

In addition for Rolyprexa 15 mg film-coated tablet: indigo carmine (E132).

What Rolyprexa looks like and contents of the pack
Rolyprexa 2.5 mg film-coated tablets are white and round (6.5 mm diameter).

Rolyprexa 5 mg film-coated tablets are white and round (8 mm diameter) with a breaking notch on one side. The film-coated tablets can be divided into equal doses.

Rolyprexa 7.5 mg film-coated tablets are white and round (9 mm diameter).

Rolyprexa 10 mg film-coated tablets are white and round (10 mm diameter) with a breaking notch on one side. The film-coated tablets can be divided into equal doses.

Rolyprexa 15 mg film-coated tablets are light blue and oval (12 mm length) with a breaking notch on both sides. The film-coated tablets can be divided into equal doses.

Rolyprexa is available in blisterpacks containing 7, 10, 14, 20, 28, 30, 35, 50, 56, 60, 70, 98, 100 or 500 film-coated tablets and in HDPE-bottles containing 50, 100, 250 or 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany
LEK S.A., ul.Podlipie 16 C, PL-95 010 Strykow, Poland.
LEK S.A., ul. Domaniewska 50 C, PL-02-672 Warszawa, Poland.
Salutas Pharma GmbH, Dieselstrasse 5, D-70839 Gerlingen, Germany.
Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana, Slovenia.

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