

## Package leaflet: Information for the user

### **Pioglitazone Rowex 15 mg Tablets** **Pioglitazone Rowex 30 mg Tablets** **Pioglitazone Rowex 45 mg Tablets**

#### Pioglitazone

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

#### **1. What Pioglitazone Rowex is and what it is used for**

Pioglitazone Rowex contains pioglitazone. It is an anti-diabetic medicine used to treat type 2 (non-insulin dependent) diabetes mellitus, when metformin is not suitable or has failed to work adequately. This is the diabetes that usually develops in adulthood.

Pioglitazone Rowex helps control the level of sugar in your blood when you have type 2 diabetes by helping your body make better use of the insulin it produces. Your doctor will check whether Pioglitazone Rowex is working 3 to 6 months after you start taking it.

Pioglitazone Rowex may be used on their own in patients who are unable to take metformin, and where treatment with diet and exercise has failed to control blood sugar or may be added to other therapies (such as insulin) which have failed to provide sufficient control in blood sugar.

#### **2. What you need to know before you take Pioglitazone Rowex**

**Do NOT take Pioglitazone Rowex if you:**

- are allergic to pioglitazone or any of the other ingredients of this medicine (listed in section 6).
- have heart failure or have had heart failure in the past.
- have liver disease.

- have had diabetic ketoacidosis (a complication of diabetes causing rapid weight loss, nausea or vomiting)
- if you have or have ever had bladder cancer.
- if you have blood in your urine that your doctor has not checked.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Pioglitazone Rowex if you:

- retain water (fluid retention) or have heart failures problems in particular if you are over 75 years old.
- have a special type of diabetic eye disease called macular oedema (swelling of the back of the eye).
- have cysts on your ovaries (polycystic ovary syndrome). There may be an increased possibility of becoming pregnant because you may ovulate again when you take Pioglitazone Rowex. If this applies to you, use appropriate contraception to avoid the possibility of an unplanned pregnancy.
- have a problem with your liver or heart. Before you start taking Pioglitazone Rowex you will have a blood sample taken to check your liver function. This check may be repeated at intervals. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with Pioglitazone Rowex and insulin experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

If you take Pioglitazone Rowex with other medicines for diabetes, it is more likely that your blood sugar could fall below the normal level (hypoglycaemia).

You may also experience a reduction in blood count (anaemia).

### **Broken bones**

A higher number of bone fractures was seen in women (but not in men) taking pioglitazone. Your doctor will take this into account when treating your diabetes.

### **Children**

Use in children under 18 years is not recommended.

### **Other medicines and Pioglitazone Rowex**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You can usually continue to take other medicines whilst you are being treated with Pioglitazone Rowex. However, certain medicines are especially likely to affect the amount of sugar in your blood:

- gemfibrozil (used to lower cholesterol)
- rifampicin (used to treat tuberculosis and other infections)

Tell your doctor or pharmacist if you are taking any of these. Your blood sugar will be checked, and your dose of Pioglitazone Rowex may need to be changed.

### **Pioglitazone Rowex with food and drink**

You may take your tablets with or without food. You should swallow the tablets with a glass of water.

### **Pregnancy and breast-feeding:**

Tell your doctor if

- you are, you think you might be or are planning to become pregnant.
- you are breast-feeding or if you are planning to breast-feed your baby.

Your doctor will advise you to stop taking this medicine.

### **Driving and using machines**

Pioglitazone will not affect your ability to drive or use machines but take care if you experience abnormal vision.

### **Pioglitazone Rowex contains lactose**

If you have been told that you have intolerance to some sugars, tell your doctor before taking Pioglitazone Rowex.

## **3. How to take Pioglitazone Rowex**

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

### **Dose**

Take one tablet of 15 mg of pioglitazone once daily.

Take one tablet of 30 mg of pioglitazone once daily.

Take one tablet of 45 mg of pioglitazone once daily.

If necessary your doctor may tell you to take a different dose.

If you feel that the effect of these tablets is too weak, talk to your doctor.

### **Taking with other medicines for diabetes**

When these tablets are taken together with other medicines used to treat diabetes (such as insulin) your doctor will tell you if you need to take a smaller dose of any of your medicines.

### **Blood tests**

Your doctor will ask you to have blood tests periodically during treatment with these tablets. This is to check that your liver is working normally.

### **Diet**

If you are following a diabetic diet, you should continue with this while you are taking these tablets.

Your weight should be checked at regular intervals; if your weight increases, inform your doctor.

### **If you take more Pioglitazone Rowex than you should**

If you accidentally take too many tablets, or if someone else or a child takes your medicine, talk to a doctor or pharmacist immediately. Your blood sugar could fall below the normal level and can be increased by taking sugar. It is recommended that you carry with you some sugar lumps, sweets, biscuits or sugary fruit juice.

### **If you forget to take Pioglitazone Rowex**

Take these tablets daily, as prescribed. However if you miss a dose, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten tablet.

### **If you stop taking Pioglitazone Rowex**

Pioglitazone Rowex should be used every day to work properly. If you stop using these tablets, your blood sugar may go up. Talk to your doctor before stopping this 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.

In particular, patients have experienced the following serious side effects:

Heart failure has been experienced commonly (may affect up to 1 in 10 people) in patients taking pioglitazone in combination with insulin. Symptoms are unusual shortness of breath or rapid increase in weight or localised swelling (oedema). If you experience any of these, especially if you are over the age of 65, seek medical advice straight away.

Bladder cancer has been experienced uncommonly (may affect up to 1 in 100 people) in patients taking pioglitazone. Signs and symptoms include blood in your urine, pain when urinating or a sudden need to urinate. If you experience any of these, talk to your doctor as soon as possible.

Localised swelling (oedema) has also been experienced very commonly in patients taking pioglitazone in combination with insulin. If you experience this side effect, talk to your doctor as soon as possible.

Broken bones have been reported commonly (may affect up to 1 in 10 people) in women patients taking pioglitazone. If you experience this side effect, talk to your doctor as soon as possible.

Blurred vision due to swelling (or fluid) at the back of the eye (frequency not known) has also been reported in patients taking pioglitazone. If you experience this symptom for the first time, talk to your doctor as soon as possible. Also, if you already have blurred vision and the symptom gets worse, talk to your doctor as soon as possible.

Allergic reactions have been reported (frequency not known) in patients taking pioglitazone. If you have a serious allergic reaction, including hives and swelling of the face, lips, tongue, or throat that may cause difficulty in breathing or swallowing stop taking this medicine and talk to your doctor as soon as possible.

The other side effects that have been experienced by some patients taking pioglitazone are:

common (may affect up to 1 in 10 people)

- respiratory infection
- abnormal vision
- weight gain
- numbness

uncommon (may affect up to 1 in 100 people)

- inflammation of the sinuses (sinusitis)
- difficulty sleeping (insomnia)

not known (frequency cannot be estimated from the available data)

- increase in liver enzymes
- allergic reactions

The other side effects that have been experienced by some patients when pioglitazone is taken with other antidiabetic medicines are:

very common (may affect more than 1 in 10 people)

- decreased blood sugar (hypoglycaemia)

common (may affect up to 1 in 10 people)

- headache
- dizziness
- joint pain
- impotence
- back pain
- shortness of breath
- small reduction in red blood cell count
- flatulence

uncommon (may affect up to 1 in 100 people)

- sugar in urine, proteins in urine
- increase in enzymes
- spinning sensation (vertigo)
- sweating
- tiredness
- increased appetite

### **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 national reporting system (see below). By reporting side effects you can help provide more information on the safety of this medicine.

Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

**FREEPOST**

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.imb.ie](http://www.imb.ie)

e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

## **5. How to store Pioglitazone Rowex**

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

Do not use this medicine after the expiry date which is stated on the carton or blister after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

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 protect the environment.

## **6. Contents of the pack and other information**

### **What Pioglitazone Rowex contains**

- The active substance(s) is  
Pioglitazone Rowex 15 mg  
Each tablet contains 15 mg pioglitazone (as pioglitazone hydrochloride).

Pioglitazone Rowex 30 mg  
Each tablet contains 30 mg pioglitazone (as pioglitazone hydrochloride).

Pioglitazone Rowex 45 mg  
Each tablet contains 45 mg pioglitazone (as pioglitazone hydrochloride).

- The other ingredient(s) are  
Lactose monohydrate,  
Hydroxypropylcellulose,  
Carmellose calcium,  
Magnesium stearate.

See end of Section 2 for further information on lactose.

### **What Pioglitazone Rowex looks like and contents of the pack**

Tablet  
Pioglitazone Rowex 15 mg  
white, round tablet, with imprint “PGT 15” on one side and with score line on both sides  
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pioglitazone Rowex 30 mg  
white, round tablet, with imprint “PGT 30” on one side and with score line on both sides  
The tablet can be divided into equal halves.

Pioglitazone Rowex 45 mg  
white, round tablet, with imprint “PGT 45” on one side and with three-part score line on the other side  
The tablet can be divided into three equal parts.

Al/Al blister: 28 tablets  
Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland

#### **Manufacturers**

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany

S.C. Sandoz, S.R.L., Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania

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

Ireland	Pioglitazone Rowex 15 mg Tablets Pioglitazone Rowex 30 mg Tablets Pioglitazone Rowex 45 mg Tablets
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The Netherlands	Pioglitazon Rowex 15 mg, tabletten Pioglitazon Rowex 30 mg, tabletten Pioglitazon Rowex 45 mg, tabletten
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**This leaflet was last revised in 09/2013**

Detailed information on this medicine is available on the web site of: [www.imb.ie](http://www.imb.ie)