

## Package leaflet: Information for the user

Pioglitazon Hexal 15 mg, tabletten  
Pioglitazon Hexal 30 mg, tabletten  
Pioglitazon Hexal 45 mg, tabletten

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 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 [Nationally completed name] is and what it is used for
2. What you need to know before you take [Nationally completed name]
3. How to take [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Contents of the pack and other information

#### 1. What [Nationally completed name] is and what it is used for

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

[Nationally completed name] 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 [Nationally completed name] is working 3 to 6 months after you start taking it.

[Nationally completed name] may be used on its 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 metformin, sulphonylurea or insulin) which have failed to provide sufficient control of blood sugar.

#### 2. What you need to know before you take [Nationally completed name]

**Do not take [Nationally completed name]:**

- if you are allergic to pioglitazone or any of the other ingredients of this medicine (listed in section 6).
- if you have heart failure or have had heart failure in the past.
- if you have liver disease.
- if you 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 [Nationally completed name] (also see section 4):

- if you retain water (fluid retention) or have heart failure problems in particular if you are over 75 years old. If you take anti-inflammatory medicines which can also cause fluid retention and swelling, you must also tell your doctor.
- if you have a special type of diabetic eye disease called macular oedema (swelling of the back of the eye).
- if you 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 [Nationally completed name]. If this applies to you, use appropriate contraception to avoid the possibility of an unplanned pregnancy.
- if you have a problem with your liver or heart. Before you start taking [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name] 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 patients, particularly women taking pioglitazone. Your doctor will take this into account when treating your diabetes.

### Children and adolescents

Use in children and adolescents under 18 years is not recommended.

### Other medicines and [Nationally completed name]

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 [Nationally completed name]. 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 [Nationally completed name] may need to be changed.

#### **[Nationally completed name] 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**

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

#### **[Nationally completed name] contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take [Nationally completed name]**

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

The usual starting dose is one tablet of 15 mg or of 30 mg of pioglitazone to be taken once daily. Your doctor may increase the dose to a maximum of 45 mg once a day. Your doctor will tell you the dose to take.

If you have the impression that the effect of [Nationally completed name] is too weak, talk to your doctor.

When these tablets are taken in combination with other medicines used to treat diabetes (such as insulin, chlorpropamide, glibenclamide, gliclazide, tolbutamide) your doctor will tell you whether you need to take a smaller dose of your medicines.

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.

If you are following a special diet for diabetes, 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 [Nationally completed name] 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 some sugar lumps, sweets, biscuits or sugary fruit juice.

**If you forget to take [Nationally completed name]**

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 [Nationally completed name]**

[Nationally completed name] 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 (may affect more than 1 in 10 people) 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 female patients taking pioglitazone and have also been reported in male patients (frequency cannot be estimated from the available data) 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 cannot be estimated from the available data) 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 cannot be estimated from the available data) 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](#)

listed in [Appendix V](#)<sup>\*</sup>. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store [nationally completed name]

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 [nationally completed name] contains

- The active substance(s) is

[nationally completed name] 15 mg

Each tablet contains 15 mg pioglitazone (as pioglitazone hydrochloride).

[nationally completed name] 30 mg

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

[nationally completed name] 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 [nationally completed name] looks like and contents of the pack

Tablet

[nationally completed name] 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.

[nationally completed name] 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.

[nationally completed name] 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.

NL/H/2057/001-002-003

Al/Al blister: 10, 14, 28, 30, 56, 90, 98, 100, 182, 196 tablets

NL/H/2058/001-002-003

Al/Al blister: 10, 14, 28, 30, 50, 56, 84, 90, 98, 100, 182, 196 tablets

NL/H/2222/001-002-003

Al/Al blister: 28 tablets

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

HEXAL AG  
Industriestrasse 25  
83607 Holzkirchen  
Germany

### **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

**Marketing Authorisation Numbers**

RVG 108644  
RVG 108645  
RVG 108646

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

NL/H/2057/001-002-003

Austria      Pioglitazon Hexal 15 mg – Tabletten  
                 Pioglitazon Hexal 30 mg – Tabletten  
                 Pioglitazon Hexal 45 mg – Tabletten

Netherlands      Pioglitazon Hexal 15 mg, tabletten  
                 Pioglitazon Hexal 30 mg, tabletten  
                 Pioglitazon Hexal 45 mg, tabletten

**Deze bijsluiter is voor het laatst goedgekeurd in september 2018.**

Meer informatie over dit geneesmiddel is beschikbaar op de website van het College ter Beoordeling van Geneesmiddelen ([www.cbg-meb.nl](http://www.cbg-meb.nl))