



PACKAGE LEAFLET:
INFORMATION FOR THE USER

PIOGLITAZONE 15 MG TABLETS PIOGLITAZONE 30 MG TABLETS PIOGLITAZONE 45 MG TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pioglitazone is and what it is used for
2. Before you take Pioglitazone
3. How to take Pioglitazone
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1. WHAT PIOGLITAZONE IS AND WHAT IT IS USED FOR

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

Pioglitazone 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 is working 3 to 6 months after you start taking it.

Pioglitazone 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 gliclazide, glibenclamide, glipizide, tolbutamide or insulin) which have failed to provide sufficient control of blood sugar.

Pioglitazone may also be used in combination with insulin.

2. BEFORE YOU TAKE PIOGLITAZONE

Do not take Pioglitazone

- if you are hypersensitive (allergic) to pioglitazone or any of the other ingredients of Pioglitazone. (See section 6 for a list of the ingredients)
- 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 has not been checked by your doctor.

Take special care with Pioglitazone

Tell your doctor before you start to take this medicine:

- 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 Pioglitazone. 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 Pioglitazone you will have a blood sample taken to check your liver function. This check will be repeated at intervals. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with Pioglitazone 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 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

Use in children under 18 years is not recommended.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You can usually continue to take other medicines whilst you are being treated with Pioglitazone. 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 may need to be changed.

Taking Pioglitazone with food and drink

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

Pregnancy and breast-feeding

Tell your doctor if

- you are pregnant, think you might be pregnant 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 discontinue 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.

Important information about some of the ingredients of Pioglitazone

This medicine contains lactose monohydrate. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Pioglitazone.

3. HOW TO TAKE PIOGLITAZONE

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 Pioglitazone is too weak, talk to your doctor. When Pioglitazone is 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 Pioglitazone. This is to check that your liver is working normally.

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

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

If you take more Pioglitazone 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 Pioglitazone

Take Pioglitazone 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

Pioglitazone should be used every day to work properly. If you stop using Pioglitazone, 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, Pioglitazone 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 (1 to 10 users in 100) 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 (1 to 10 users in 1000) 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 (1 to 10 users in 100) 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 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 patients taking Pioglitazone are:

common (affects 1 to 10 users in 100)

- respiratory infection
- abnormal vision
- weight gain
- numbness

uncommon (affects 1 to 10 users in 1,000)

- 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 (affects more than 1 user in 10)
- decreased blood sugar (hypoglycaemia)

common (affects 1 to 10 users in 100)

- headache
- dizziness
- joint pain

- impotence
- back pain
- shortness of breath
- small reduction in red blood cell count
- flatulence (wind)

uncommon (affects 1 to 10 users in 1,000)

- 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PIOGLITAZONE

Keep out of the reach and sight of children.

Do not use Pioglitazone after the expiry date which is stated on the carton and the blister pack after the word "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage precautions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Pioglitazone contains

- The active substance is pioglitazone. Each tablet contains 15 mg, 30 mg or 45 mg of pioglitazone (as hydrochloride).
- The other ingredients are lactose monohydrate, hydroxypropylcellulose, croscarmellose sodium, magnesium stearate.

What Pioglitazone looks like and contents of the pack

15 mg: White to almost white round tablets with beveled edges, engraved "15" on one side (diameter 7.0 mm).

30 mg: White to almost white round tablets with beveled edges (diameter 8.0 mm).

45 mg: White to almost white round tablets with beveled edges, engraved "45" on one side (diameter 10.0 mm).

The tablets are available in boxes of 14, 28, 30, 56, 60, 90 and 98 tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Consilient Health Ltd., 5th Floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland.

Manufacturers

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This leaflet was last revised in August 2016.