

Package leaflet: Information for the user

Pioglitazone 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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1. What Pioglitazone Tablets are and what they are used for

Pioglitazone Tablets contain 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 Tablets help 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 Tablets are working 3 to 6 months after you start taking it.

Pioglitazone Tablets 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 metformin, sulphonylurea or insulin) which have failed to provide sufficient control of blood sugar.

2. What you need to know before you take Pioglitazone Tablets

Do not take Pioglitazone Tablets

- 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

Tell your doctor, pharmacist or nurse before taking Pioglitazone Tablets:

- 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 Tablets. 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 Tablets 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 Tablets 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 Tablets 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.

Other medicines and Pioglitazone Tablets

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 Tablets. 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 Tablets may need to be changed.

Pioglitazone Tablets with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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.

Pioglitazone Tablets contain lactose monohydrate

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Pioglitazone Tablets.

3. How to take Pioglitazone Tablets

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 Tablets is too weak, talk to your doctor.

When Pioglitazone Tablets 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 Tablets. 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 Tablets.

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

If you take more Pioglitazone Tablets 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 Tablets

Take Pioglitazone 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 Tablets

Pioglitazone Tablets should be used every day to work properly. If you stop using Pioglitazone 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, pharmacist or nurse.

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 (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 (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 (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 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 Tablets. 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 anti-diabetic 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.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

5. How to store Pioglitazone Tablets

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

This medicinal product does not require any special storage conditions.

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

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 Tablets contain

- The active substance is pioglitazone. Each Pioglitazone 45 mg tablet contains 45 mg of pioglitazone (as hydrochloride).
- The other ingredients are lactose monohydrate, hydroxypropylcellulose, carmellose calcium and magnesium stearate.

What Pioglitazone Tablets looks like and contents of the pack

Pioglitazone 45 mg Tablets are round, convex and white. Pioglitazone 45 mg Tablets are provided in blister packs of 14, 28, 30, 56, 84, 90 and 98 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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