

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Pioglitazone hydrochloride 30 mg or 45 mg Tablets

Pioglitazone hydrochloride
(referred to as Pioglitazone Tablets in the remainder of this leaflet)



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 of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pioglitazone Tablets are and what they are used for
2. What you need to know before you take Pioglitazone Tablets
3. How to take Pioglitazone Tablets
4. Possible side effects
5. How to store Pioglitazone Tablets
6. Contents of the pack and other information

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

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

Pioglitazone Tablets 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 in 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 Pioglitazone Tablets (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, pharmacist or nurse before taking Pioglitazone Tablets if any of the following applies to you (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 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 and adolescents

Use in children under 18 years is not recommended.

Other medicines and Pioglitazone Tablets

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

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 and drink

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

Pregnancy and breastfeeding

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 discontinue 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.

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, pharmacist or nurse if you are not sure.

The recommended dose is one tablet of 30 mg or 45 mg of pioglitazone to be taken once daily. If necessary your doctor may tell you to take a different dose.

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, glizalide, 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 special diet for diabetes, 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 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 Tablets 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 Tablets. 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 Tablets 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 Tablets and have also been reported in male patients (frequency cannot be estimated from the available data) taking Pioglitazone Tablets. 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 Tablets. 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 Tablets 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 Tablets 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website:

<http://www.mhra.gov.uk/yellowcard>

Ireland:

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 Pioglitazone Tablets

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 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.

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 contains

The active substance is pioglitazone hydrochloride.

Each 30mg tablet contains 33.06mg pioglitazone hydrochloride, equivalent to 30mg pioglitazone.

Each 45mg tablet contains 49.59mg pioglitazone hydrochloride, equivalent to 45mg pioglitazone.

The other ingredients are lactose monohydrate, carboxymethylcellulose calcium, hydroxypropyl cellulose and magnesium stearate

What Pioglitazone Tablets looks like and contents of the pack

Pioglitazone Tablets 30 mg tablets are white to off-white, round, flat beveled tablet debossed with 'W 977' on one side and plain on other side.

Pioglitazone Tablets 45 mg tablets are white to off-white, round, flat beveled tablet debossed with 'W 978' on one side and plain on other side.

The tablets are supplied in blister packs of 28, 56 or 84 tablets. Not all the pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Wockhard UK Ltd, Ash Road North, Wrexham, LL13 9UF

Manufacturer:

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF.

This Medicinal Product is authorised in the Member States under the following names:

UK and Ireland: Pioglitazone hydrochloride 30mg, 45mg Tablets

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

| Product name | Reference number |
|---|------------------|
| Pioglitazone hydrochloride 30mg Tablets | 29831/0528 |
| Pioglitazone hydrochloride 45mg Tablets | 29831/0529 |

This is a service provided by the Royal National Institute of Blind People. For the Republic of Ireland please call +44 1978 661 261

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