
Package leaflet: Information for the patient**Pioglitazone 15 mg tablets****Pioglitazone 30 mg tablets****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 further questions, please ask your doctor or your 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Pioglitazone is and what it is used for

Pioglitazone contains pioglitazone. It is an anti-diabetic medicine used to treat type 2 (non-insulin dependent) diabetes mellitus. 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** is working 3 to 6 months after you start taking it.

Pioglitazone tablets may be used on its own or in combination with metformin and/or a sulphonylurea which are also oral anti-diabetic medicines.

Pioglitazone tablets may also be used in combination with insulin.

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

Talk to your doctor or pharmacist or nurse before taking **Pioglitazone**

- If you retain water (fluid retention) or have had heart failures problems in particular if you are over 75 years old.

- 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 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 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** 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 localized 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 women (but not in men) 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

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**. 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** needs to be changed.

Pioglitazone tablets with food and drink and alcohol:

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

Pregnancy and breastfeeding and fertility:

Tell your doctor if

- you are, you think you might be or are planning to become pregnant.
- you are breastfeeding 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.

Pioglitazone contains lactose

This medicinal product contains lactose. 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

One tablet of 15 mg, 30 mg or 45 mg pioglitazone should 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 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 **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 tablets.

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

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

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 sugar 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 taking Pioglitazone your blood sugar may go up. Talk to your doctor before stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor or 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 (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 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.

The other side effects that have been experienced by some 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.

The other side effects 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
- blood in urine
- back pain
- shortness of breath
- small reduction in red blood cell count
- flatulence

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

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

5. How to store Pioglitazone

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 data refers to the last day of that month.

This medicinal product does not require any special storage precautions.

Do not throw away any medicines or 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 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, carmellose calcium, hydroxypropyl cellulose and magnesium stearate.

What Pioglitazone looks like and contents of the pack

Pioglitazone 15 mg: white to off-white, round, flat faced beveled edge uncoated tablets debossed with '15' on one side and plain on the other side.

Pioglitazone 30 mg: white to off-white, round, flat faced beveled edge uncoated tablets with breakline on both sides. The tablet can be divided into equal halves.

Pioglitazone 45 mg: white to off-white, round, flat faced beveled edge uncoated tablets debossed with 'T' shape breakline on both sides. The tablet can be divided into equal thirds.

Triplex (PVC/PE/PVdC)/Al blisters or OPA/Al/PVC/Al blisters

Packs of 28, 30, 50, 98, 120 and 200 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Heumann Pharma GmBH & Co. Generica KG, Südwestpark 50, 90449 Nürnberg, Germany

Manufacturers

Torrent Pharma GmbH, Südwestpark 50, 90449 Nürnberg, Germany

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

NL: Pioglitazon Torrent 15/30/45 mg tabletten

UK: Pioglitazone 15/30/45 mg tablets

DE: Pioglitazon Heumann 15/30/45 mg Tabletten

LT: Pioglitazono Torrent 15/30/45 mg tabletės

RO: Pioglitazona Torrent 15/30/45 mg comprimate

IT: Pioglitazone Torrent

This leaflet was last revised in 10/2011