Package leaflet: Information for the patient

Pioglitazone 15 mg tablets
Pioglitazone 30 mg tablets
Pioglitazone 45 mg tablets

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 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 tablets contain 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.
- 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 is 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 insulin) which have failed to provide sufficient control in blood sugar.

2. What you need to know before you take Pioglitazone

Do not take Pioglitazone if:
- you are allergic to pioglitazone or any of the other ingredients of this medicine (listed in section 6),
- you have heart failure or have had heart failure in the past,
- you have liver disease,
- you have had diabetic ketoacidosis (a complication of diabetes causing rapid weight loss, nausea or vomiting),
- you have or have ever had bladder cancer,
- you have blood in your urine that your doctor has not checked.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pioglitazone:
- If you retain water (fluid retention) or have heart problems in particular if you are over 75 years old. If you take non-steroidal anti-inflammatory medicines which can also cause water (fluid retention) and swelling, including celecoxib or etoricoxib, you must also tell your doctor.
- If you have ever had blood in your urine. If you find blood in your urine or have other problems urinating while taking pioglitazone, you should contact your doctor.
- If you smoke (or have smoked in the past), have received chemotherapy or radiotherapy (for cancer treatment).
- If you have a special type of diabetic eye disease called macular oedema (swelling of the back of the eye with worsening of your vision).
- 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 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 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 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 tablets. However, certain medicines are especially likely to affect the amount of sugar in your blood like:
- 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.

Pregnancy and breast-feeding

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.
You should not take pioglitazone in pregnancy as it is unsure whether the medicine can affect the growth of your baby.
You should not take pioglitazone if you are breast-feeding as it is not known whether it may be present in the milk.

Driving and using machines

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

Pioglitazone tablets contain lactose and sodium.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially `sodium-free'.

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 15 mg or 30 mg of pioglitazone taken once daily. Your dose might be increased to a maximum of 45 mg of pioglitazone taken once daily. Swallow your tablet with a glass of water with or without food.

If necessary your doctor may tell you to take a different dose. If you have the impression that the effect of your prescribed strength of Pioglitazone 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.

Description	Pioglitazone Hydrochloride 45 mg,15 mg,30 mg 28			Date: 19 AUG 2020	Time: 12:50
Component Type	Leaflet	Pharma Code	6414	No. of colours 1	Page Count 1/2
Affiliate Item Code	2243866	SAP No.	400505309 400505310 400505311	Colours Black	
Superceded Affiliate Item Code	946161	Vendor Job No.	563198	Non-Print Colours	
TrackWise PR No.	2243866	Trackwise Proof No.	2	Equate CMYK with	
MA No.	PL 04569/1245 -1247	Client Market	United Kingdom		
Packing Site/Printer	N/A	Keyline/Drawing No.	NA		

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 tablets than you should
If you accidentally take too many tablets, or if someone else or a child takes your medicine, contact your doctor or hospital emergency department **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 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 dose.

If you stop taking Pioglitazone tablets
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, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:
- Heart failure (when taking pioglitazone in combination with insulin): symptoms are unusual shortness of breath or rapid increase in weight or localised swelling (oedema).
- Bladder cancer: signs and symptoms include blood in your urine, pain when urinating or a sudden need to urinate.
- Localised swelling (oedema) (when taking pioglitazone in combination with insulin).
- Broken bones (this has been reported in both female and male patients).
- Blurred vision due to swelling (or fluid) at the back of the eye. Also, if you already have blurred vision and the symptom gets worse, talk to your doctor as soon as possible.
- Allergic reactions: symptoms of a serious allergic reaction include hives and swelling of the face, lips, tongue, or throat that may cause difficulty in breathing or swallowing.

Other possible side effects:
Common: may affect up to 1 in 10 people:
- abnormal vision
- respiratory infection
- 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 following additional side effects have been experienced by some patients when Pioglitazone is taken with other antidiabetic medicines.

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 (anemia)
- flatulence
- increase in enzyme levels

Uncommon: may affect up to 1 in 100 people:
- sugar in urine, proteins in urine
- 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 this medicine out of the sight and reach of children.

Blisters: This medicine does not require any special storage conditions.
Bottles: Once open keep the bottle tightly closed in order to protect from moisture.

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

Bottles: Use within 90 days of opening.
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. Content of the pack and other information

What Pioglitazone contains
The active substance is pioglitazone. Each tablet contains 15 mg, 30 mg, 45 mg of pioglitazone (as hydrochloride).

The other ingredients are lactose monohydrate, hypromellose (E464), silica colloidal anhydrous, croscarmellose sodium, polysorbate 80 (E433), magnesium stearate.
(see section 2 `Pioglitazone Mylan contains lactose and sodium')

What Pioglitazone looks like and contents of the pack
Pioglitazone 15 mg Tablets are white to off –white, round biconvex, uncoated tablets, debossed with "PG" over "15" on one side and "G" on the other side.

Pioglitazone 30 mg Tablets are white to off –white, round biconvex, uncoated tablets, debossed with "PG" over "30" on one side and "G" on the other side.

Pioglitazone 45 mg Tablets are white to off –white, round biconvex, uncoated tablets, debossed with "PG" over "45" on one side and "G" on the other side.

Pioglitazone is available in blisters packs containing 10, 14, 28, 30, 56, 84, 90, 98 tablets and in bottles containing 500 tablets (hospital pack). Do not eat the desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan,
Potters Bar,
Hertfordshire,
EN6 1TL,
United Kingdom.

Manufacturers
Gerard Laboratories,
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland.

Mylan Hungary Kft.,
H-2900 Komárom,
Mylan utca 1,
Hungary.

This leaflet was last revised in
08/2020

2243866
50074994

Description	Pioglitazone Hydrochloride 45 mg,15 mg,30 mg 28			Date: 19 AUG 2020	Time: 12:50
Component Type	Leaflet	Pharma Code	6414	No. of colours 1	Page Count 2/2
Affiliate Item Code	2243866	SAP No.	400505309 400505310 400505311	Colours Black	
Superceded Affiliate Item Code	946161	Vendor Job No.	563198	Non-Print Colours	
TrackWise PR No.	2243866	Trackwise Proof No.	2	Equate CMYK with	
MA No.	PL 04569/1245 -1247	Client Market	United Kingdom		
Packing Site/Printer	N/A	Keyline/Drawing No.	NA		