

APOTEX-Pioglitazone

Pioglitazone hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about pioglitazone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Pioglitazone is used to treat type 2 diabetes not controlled by diet and exercise. It helps to improve the action of insulin produced by your body.

Pioglitazone belongs to a group of medicines called glitazones.

Glitazones decrease insulin resistance and help to control the level of glucose in your blood when you have type 2 diabetes. This is the 'adult onset' type of diabetes and is usually controlled by diet, certain oral medications and occasionally insulin.

Pioglitazone can be used alone (when diet and exercise is not enough to treat your diabetes) or together with other anti-diabetic medicines.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- pioglitazone
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have or have had any of the following medical conditions:

- heart failure
- type 1 diabetes mellitus
- diabetic ketoacidosis

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease with shortness of breath after minimal physical activity
- heart disease with severe symptoms at rest
- swelling of hands, ankles or feet
- liver problems
- kidney problems requiring dialysis
- bone fractures, usually in the hand, upper arm or foot
- bladder cancer, or symptoms such as blood in the urine, often accompanied by pain, burning or sudden urges to urinate

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Pioglitazone is not recommended for use during pregnancy and breastfeeding. It is not known whether pioglitazone passes into breast milk.

Your doctor will discuss with you the risks and benefits involved.

Some premenopausal women who do not have monthly periods may restart their periods when taking pioglitazone.

These women may have an increased risk of pregnancy. Your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you are taking other medicines for diabetes. Pioglitazone can enhance the action of other medicines, causing an increased risk of low blood sugar (hypoglycaemia). Your doctor may adjust the dose of your medicines.

Tell your doctor if you suffer from lactose intolerance.

APOTEX- pioglitazone tablets contain lactose.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and pioglitazone may interfere with each other. These include:

- gemfibrozil
- medicines to treat diabetes (e.g. glibenclamide, gliclazide, insulin, metformin, chlorpropamide or tolbutamide)
- oral contraceptives
- rifampicin

These medicines may be affected by pioglitazone or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking pioglitazone.

Other interactions not listed above may also occur.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand any instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you will need to take.

This depends on your condition and whether you are taking any other medicines.

Pioglitazone tablets should be taken once a day.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much pioglitazone.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking pioglitazone.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking pioglitazone.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you have gained weight since taking pioglitazone.

Weight gain can be associated with improved blood sugar control; however, it may also be a symptom of heart failure.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen, or you may have unwanted side effects.

Things to be careful of

Be careful to avoid low blood sugar levels (hypoglycaemia) whilst driving or operating machinery, especially if using pioglitazone in combination with other diabetes medicines.

If your blood glucose level becomes too low, you may feel dizzy, lightheaded, weak or tired, and your reaction time may be slower than usual. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, e.g. sugar sachets or jelly beans
- carry emergency food rations in case of a delay, e.g. dried fruit, biscuits or muesli bars

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking pioglitazone.

This medicine helps most people with type 2 diabetes mellitus, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following:

- a small increase in weight
- signs of low blood sugar levels (hypoglycaemia) such as weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger, numbness around the lips and fingers

Tell your doctor as soon as possible if you notice any of the following:

- blood in the urine, often accompanied by pain and burning
- eye problems, including blurred or double vision.
- macular oedema (an eye disorder that can affect vision)

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- dark urine or pale stools, yellowing of the skin or eyes, severe cramps of the stomach, nausea or vomiting, loss of weight, tiredness (altered or impaired liver function)
- heart failure, which may show as swelling of the ankles, feet and hands (oedema) and/or fluid in the lungs (pulmonary oedema). This has been reported in clinical trials mainly in patients who are taking pioglitazone in combination with insulin
- shortness of breath when at rest or after minimal physical activity with swelling of legs, feet and hands or rapid increase in weight
- bone fracture

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Storage and disposal

Storage

Keep the tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What APOTEX- Pioglitazone looks like

15 mg tablets:

White to off-white, round, biconvex, uncoated tablet embossed "15" on one side and plain on the other side. AUST R 166911.

30 mg tablets:

White to off-white, round, flat, bevelled edged, uncoated tablets embossed "30" on one side and plain on the other side.

AUST R 166914.

45 mg tablets:

White to off-white, round, flat, bevelled edged, uncoated tablet embossed "45" on one side and plain on the other side.

AUST R 166913.

Available in blister packs of 7, 28, 50 or 98 tablets.

*Not all strengths and/or pack sizes may be available.

Ingredients

Each tablet contains 15 mg, 30 mg or 45 mg of pioglitazone hydrochloride as the active ingredient.

It also contains the following:

- lactose monohydrate
- carmellose calcium
- hyprolose
- magnesium stearate.

This medicine does not contain gluten, sucrose, tartrazine and other azo dyes.

Sponsor

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