

## APOTEX-Pioglitazone

Contains the active ingredient, pioglitazone hydrochloride

### Consumer Medicine Information

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

#### What is in this leaflet

**Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.**

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.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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.

**Keep this leaflet with your medicine.**

You may want to read it again.

#### What pioglitazone is used for

The name of your medicine is APOTEX-Pioglitazone. It contains the active ingredient, pioglitazone hydrochloride.

Pioglitazone belongs to a group of medicines called glitazones. Glitazones decrease insulin resistance.

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

#### How it works

Pioglitazone helps 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 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 pioglitazone for another reason.

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

#### Use in children

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

#### Before you take pioglitazone

##### When you must not take it

**Do not take this medicine if:**

- you have heart failure requiring treatment. Talk to your doctor if you have heart failure.
- you have type 1 diabetes.
- you have had an allergic reaction to pioglitazone or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

**Do not take this medicine after the expiry date (EXP) printed on the pack.**

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.**

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:**

**1. You have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**2. You have or have had any medical conditions, especially the following:**

- bladder cancer or symptoms associated with bladder cancer such as blood in the urine (haematuria), often accompanied by pain and burning
- type 1 diabetes or diabetic ketoacidosis
- heart disease with shortness of breath after minimal physical activity
- heart disease with severe symptoms at rest
- swelling of hands, ankles or feet
- problems with your liver
- problems with your kidneys that requires dialysis (pioglitazone is not recommended for use if you are on dialysis)
- for women with diabetes, insulin can interfere with their ability to become pregnant
- some women who do not have monthly periods and have not been through menopause may restart their periods when taking pioglitazone - these women may be at increased risk of pregnancy
- bone fractures, usually in the hand, upper arm or foot, have been seen in some women when taking pioglitazone. Talk to your doctor for advice on how to keep your bones healthy.

**3. You plan to become pregnant or breast-feed.**

Like most medicines, pioglitazone is not recommended for use during pregnancy. If there is a need to consider taking pioglitazone during your pregnancy, your doctor will discuss with you the benefits and risks of taking it.

It is recommended that you do not breast-feed while taking pioglitazone, as it is not known whether it passes into breast milk.

**Tell your doctor if you are using another medicine for diabetes. Pioglitazone can enhance the action of other medicines. You may be at risk of low blood sugar (hypoglycaemia).**

If this happens, your doctor may need to adjust the dose of your other medicines.

**Tell your doctor if you suffer from lactose intolerance because 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 buy without a prescription from your pharmacy, supermarket or health food shop.

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

- chlorpropamide
- gemfibrozil
- glibenclamide
- gliclazide
- insulin
- metformin
- oral contraceptives
- rifampicin
- tolbutamide.

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 can tell you if you are taking any of these medicines. They may also 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 be different to the information in this leaflet.

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

#### How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

Pioglitazone tablets should be taken once a day as advised by your doctor.

Your doctor may increase or decrease your dose in order to find the right dose for your condition.

#### How to take it

Pioglitazone tablets should be swallowed whole with a glass of water.

#### When to take it

Take the tablets at about the same time each day.

Taking your medicine 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 it before, with 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 (tel: 13 11 26 in Australia) for advice, or go to the Accident and Emergency Department 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.

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### While you are taking pioglitazone

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#### *Things you must do*

It is important that you remember to take pioglitazone daily and at the dose prescribed by your doctor.

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

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

Tell your doctor immediately if you become pregnant.

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.

Go to your doctor regularly for a check-up.

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 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 give this medicine to anyone else, even if their symptoms seem similar to yours.

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

Do not stop taking your medicine, or change 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*

Pioglitazone is unlikely to affect your ability to drive or operate machinery. However, be careful to avoid hypoglycaemia whilst driving or operating machinery if using pioglitazone in combination with other diabetes medicines.

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### Side effects of pioglitazone

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All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. You may need medical attention if you get some of the side effects.

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

This medicine helps most people with type 2 diabetes not controlled by diet, but it may have unwanted side effects in some people.

Some side effects may be related to the dose of pioglitazone. Therefore, it is important that you tell your doctor, as soon as possible, about any unwanted effects. Your doctor may then decide to adjust the dose of pioglitazone you are taking.

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

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

#### **Tell your doctor if you notice any of the following side effects:**

- an 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
- 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
- eye problem including blurred or double vision.

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

- blood in the urine often accompanied by pain and burning, these can be symptoms of bladder cancer
- bone fracture (mainly in women)
- dark urine or pale stools, yellowing of the skin or eyes, severe cramps of the stomach, nausea or vomiting, loss of weight, tiredness
- shortness of breath when at rest or after minimal physical activity with swelling of legs, feet and hands, rapid increase in weight.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

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

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### After taking this medicine

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#### *Storage*

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay 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.

#### *Where to go for further information*

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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### Product description

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#### *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.

##### **30 mg tablets:**

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

##### **45 mg tablets:**

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

#### *Ingredients*

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

It also contains the following inactive ingredients:

- lactose
- carmellose calcium
- hydroxypropylcellulose
- magnesium stearate.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

#### *Australian Registration Numbers*

- APOTEX-Pioglitazone 15 mg tablets (blister): AUST R 166911.
- APOTEX-Pioglitazone 30 mg tablets (blister): AUST R 166914.
- APOTEX-Pioglitazone 45 mg tablets (blister): AUST R 166913.

#### *Sponsor*

##### **Apotex Pty Ltd**

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