

## PRIOTEN 15, 30 & 45

*Pioglitazone hydrochloride*

### Consumer Medicine Information

#### What is in this leaflet

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

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking PRIOTEN 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 this medicine**

You may need to read it again..

#### What PRIOTEN used for

PRIOTEN is a tablet that is used to improve the action of the body's naturally produced insulin. PRIOTEN is used in the management of type 2 diabetes not controlled by diet.

PRIOTEN 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.

This medicine is also called pioglitazone hydrochloride and belongs to a group of medicines called glitazones. Glitazones decrease insulin resistance.

**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.

PRIOTEN can be used alone (when diet and exercise is not enough to treat

your diabetes) or together with other anti-diabetic medicines.

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

The use of PRIOTEN has not been studied in children.

#### Before you take PRIOTEN

##### *When you must not take PRIOTEN*

**Do not take PRIOTEN if:**

- you have heart failure requiring treatment. Talk to your doctor if you have heart failure
- you have type 1 diabetes or diabetic ketoacidosis (often caused by very high blood glucose levels)
- you have an allergy to any medicine containing pioglitazone hydrochloride or any of the ingredients listed at the end of this leaflet (see 'Product Description').

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 after the 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.**

##### *Before you start to take PRIOTEN*

**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
- bladder cancer or symptoms associated with bladder cancer such as blood in the urine (hematuria) often accompanied by pain and burning
- problems with your liver
- problems with your kidneys that requires dialysis. PRIOTEN is not recommended for use if you are on dialysis
- some women who do not have monthly periods and have not been through menopause may restart their periods when taking PRIOTEN. 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 PRIOTEN. Talk to your doctor for advice on how to keep your bones healthy.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Like most medicines, PRIOTEN is not recommended for use during pregnancy. If there is a need to consider PRIOTEN during your pregnancy, your doctor will discuss with you the benefits and risks of taking PRIOTEN. It is recommended that you do not breast-feed while taking PRIOTEN, as it is not known whether PRIOTEN passes into breast milk.

**Tell your doctor if you are using another medicine for diabetes. PRIOTEN 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 PRIOTEN contain lactose).**

**If you have not told your doctor about any of the above, tell him/her before you start taking PRIOTEN.**

##### *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 PRIOTEN may interfere with each other. These include:

- Chlorpropamide
- gemfibrozil
- glibenclamide
- gliclazide
- insulin
- metformin
- oral contraceptives
- rifampicin
- tolbutamide

These medicines may be affected by PRIOTEN 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 or pharmacist has more information on medicines to be careful with or to avoid while taking this medicine.

#### How to take PRIOTEN

**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 the instructions on the carton, ask your doctor or pharmacist for help.**

##### *How much to take PRIOTEN*

Your doctor will tell you how many PRIOTEN tablets you should take. The dose your doctor will prescribe for you will usually be in the range of 15 mg to 45 mg per day.

**PRIOTEN 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 appropriate dose for your condition.

##### *How to take PRIOTEN*

**PRIOTEN should be swallowed whole with a glass of water.**

##### *When to take PRIOTEN*

**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 PRIOTEN*

**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.

##### *If you forget to take PRIOTEN*

**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.**

**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 Australian Poisons Information Centre (13 11 26) or the New Zealand National Poisons Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much PRIOTEN. 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 PRIOTEN

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### *Things you must do*

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

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

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

**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 do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**Tell your doctor if you have gained weight since taking PRIOTEN.**

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 PRIOTEN to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if their symptoms seem similar to yours or 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*

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

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you experience any undesirable effect or feel unwell while you are taking PRIOTEN.**

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

Some side effects may be related to the dose of PRIOTEN. Accordingly, 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 PRIOTEN you are taking.

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

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

A few patients have experienced the following side effects whilst taking PRIOTEN:

- a small increase in weight
- low blood sugar levels (hypoglycaemia). This occurs more often when PRIOTEN is taken with a sulfonylurea or insulin
- heart failure which may show as localised 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
- increased risk of fracture in women
- macular oedema (an eye disorder that can affect vision)
- altered or impaired liver function.

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

- weight gain
- signs of hypoglycaemia which may include weakness, trembling or shaking, sweating, lightheadedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger, numbness around the lips and fingers
- eye problems including blurred or double vision.

The above list includes the more common side effects of your medicine.

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

- 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
- blood in the urine often

accompanied by pain and burning, these can be symptoms of bladder cancer

The above list includes serious side effects, which may require medical attention. Serious side effects are 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.

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## After Taking PRIOTEN

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### *Storage*

**Keep your tablets in the aluminium blister pack until it is time to take them.**

**Keep your tablets in a cool, dry place where the temperature stays below 25°C.**

**Do not store PRIOTEN 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 tells you to stop taking PRIOTEN or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product Description

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### *What PRIOTEN looks like*

PRIOTEN 15, 30 & 45 is presented in pack size of 28 tablets in blister.

- PRIOTEN 15 (AUST R 176384) White to off white, round, biconvex, uncoated tablets, debossed with '31' on one side and 'H' on the other side.
- PRIOTEN 30 (AUST R 176385) White to off white, round, flat faced, bevel edge, uncoated tablets, debossed with '32' on one side and 'H' on the other side.
- PRIOTEN 45 (AUST R 176382) White to off white, round, flat faced, bevel edge, uncoated tablets, debossed with '33' on one side and 'H' on the other side.

### *Ingredients*

#### **Active Ingredient:**

Pioglitazone (as hydrochloride). Each tablet may contain either 15 mg, 30 mg & 45 mg of pioglitazone as hydrochloride.

#### **Other Ingredients :**

- Lactose
- Carmellose calcium
- Hydroxypropylcellulose
- Magnesium stearate

Please read this leaflet carefully before you start taking PRIOTEN. You may wish to keep it to read again.

### *Name and Address of the Sponsor*

#### **Aurobindo Pharma Australia Pty Ltd**

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#### **Date of Approval**

6 December 2011