

ARX-PIOGLITAZONE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking ARX-PIOGLITAZONE?

ARX-PIOGLITAZONE contains the active ingredient pioglitazone hydrochloride. ARX-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.

For more information, see Section [1. Why am I taking ARX-PIOGLITAZONE?](#) in the full CMI.

2. What should I know before I take ARX-PIOGLITAZONE?

Do not use if you have ever had an allergic reaction to ARX-PIOGLITAZONE or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take ARX-PIOGLITAZONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-PIOGLITAZONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take ARX-PIOGLITAZONE?

- 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. ARX-Pioglitazone tablets should be taken once a day.
- Follow the directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

More instructions can be found in Section [4. How do I take ARX-PIOGLITAZONE?](#) in the full CMI.

5. What should I know while taking ARX-PIOGLITAZONE?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, pharmacist, surgeon or anaesthetist you visit that you are taking ARX-PIOGLITAZONE.If you become pregnant while taking ARX-PIOGLITAZONE, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">Do not stop taking ARX-PIOGLITAZONE or change the dosage without first checking with your doctor
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how ARX-PIOGLITAZONE affects you.
Looking after your medicine	<ul style="list-style-type: none">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.

For more information, see Section [5. What should I know while taking ARX-PIOGLITAZONE?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: 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 finger, 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). Serious side effects: 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARX-PIOGLITAZONE

Active ingredient(s): *pioglitazone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ARX-PIOGLITAZONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ARX-PIOGLITAZONE.**

Where to find information in this leaflet:

- [1. Why am I taking ARX-PIOGLITAZONE?](#)
- [2. What should I know before I take ARX-PIOGLITAZONE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ARX-PIOGLITAZONE?](#)
- [5. What should I know while taking ARX-PIOGLITAZONE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking ARX-PIOGLITAZONE?

ARX-PIOGLITAZONE contains the active ingredient pioglitazone hydrochloride.

ARX-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.

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

ARX-PIOGLITAZONE is only available with a doctor's prescription. ARX-PIOGLITAZONE is not addictive.

2. What should I know before I take ARX-PIOGLITAZONE?

Warnings

Do not use ARX-PIOGLITAZONE if:

- you are allergic to pioglitazone hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Symptoms of allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of face, lips, tongue or other parts of the body.

Check with 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
- 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
- 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.
- suffer from lactose intolerance. ARX-PIOGLITAZONE tablets contain lactose.
- are pregnant or if you plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.
- take any medicines for any other condition.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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:

- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARX-PIOGLITAZONE.

4. How do I take ARX-PIOGLITAZONE?

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.
- **ARX-Pioglitazone tablets should be taken once a day.**
- Follow the directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

When to use ARX-PIOGLITAZONE

- **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 to take ARX-PIOGLITAZONE

- Swallow the tablets whole with a full glass of water

How long take ARX-PIOGLITAZONE

- Follow the instructions provided and use ARX-PIOGLITAZONE 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 ARX-PIOGLITAZONE

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 you missed.

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

If you use too much ARX-PIOGLITAZONE

If you think that you have used too much ARX-PIOGLITAZONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ARX-PIOGLITAZONE?

Things you should do

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking ARX-PIOGLITAZONE.

Remind any doctor, dentist, or pharmacist you visit that you are taking ARX-PIOGLITAZONE.

If you are going to have a surgery, tell the surgeon or anaesthetist that you are taking ARX-PIOGLITAZONE. It may affect other medicines used during surgery.

Call your doctor straight away if you:

- become pregnant while taking ARX-PIOGLITAZONE.
- 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.
- 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.

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.

Things you should 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 jellybeans
- carry emergency food rations in case of a delay, e.g. dried fruit, biscuits or muesli bars

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-PIOGLITAZONE affects you.

Looking after your medicine

- 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.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 finger. <p>Tell your doctor as soon as possible if you notice any of the following</p> <ul style="list-style-type: none"> • 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) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ARX-PIOGLITAZONE contains

Active ingredient (main ingredient)	15 mg, 30 mg or 45 mg of pioglitazone hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• carmellose calcium• hypolose• magnesium stearate
Potential allergens	Contains sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What ARX-PIOGLITAZONE looks like

ARX-PIOGLITAZONE 15mg tablets - White to off-white, round, biconvex, uncoated tablet embossed "15" on one side and plain on the other side. (Aust R 166911).

ARX-PIOGLITAZONE 30mg 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).

ARX-PIOGLITAZONE 45mg 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.

Who distributes ARX-PIOGLITAZONE

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel St

Cremorne VIC 3121

Australia

www.arrotex.com.au

This leaflet was prepared in September 2024.