

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 using ACTOS?

ACTOS contains the active ingredient pioglitazone hydrochloride. ACTOS is used in the management of type 2 diabetes not controlled by diet.

For more information, see Section [1. Why am I using ACTOS?](#) in the full CMI.

2. What should I know before I use ACTOS?

Do not use if you have ever had an allergic reaction to pioglitazone hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist 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 use ACTOS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ACTOS 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 use ACTOS?

- ACTOS should be taken at the same time every day to ensure it works effectively.
- Follow all instructions given to you by your doctor.

More instructions can be found in Section [4. How do I use ACTOS?](#) in the full CMI.

5. What should I know while using ACTOS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ACTOS.• Monitor your health and contact your doctor if you notice any changes.• Keep all of your doctor's appointments and go for regular check-ups.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">• ACTOS may cause dizziness in some people. Do not drive or operate machines until you know how this medicine affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store ACTOS in a cool dry place, out of direct light, where the temperature is below 25°C.• Keep ACTOS in the original packaging, in a safe place, away from children.

For more information, see Section [5. What should I know while using ACTOS?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include: weight gain; signs of low blood sugar (hypoglycaemia); eye problems; bone fracture; and impaired liver function. Serious side effects may include: dark urine; pale stools; yellowing skin or eyes; severe stomach cramps; nausea or vomiting; weight loss; tiredness; shortness of breath with swelling of legs, feet and hands, with rapid increase in weight; signs of bladder cancer; and oedema (signs of heart failure).

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.

ACTOS®

Active ingredient(s): pioglitazone hydrochloride

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using ACTOS?

ACTOS contains the active ingredient pioglitazone hydrochloride. ACTOS belongs to a group of medicines called glitazones. Glitazones decrease insulin resistance.

ACTOS is used in the management of type 2 diabetes not controlled by diet.

ACTOS is a tablet that is used to improve the action of the body's naturally produced insulin. ACTOS 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. ACTOS can be used alone (when diet and exercise is not enough to treat your diabetes) or together with other anti-diabetic medicines.

Your doctor may have prescribed it for another purpose.

2. What should I know before I use ACTOS?

Warnings

Do not use ACTOS 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. 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.

- 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).

Check with your doctor if you have:

- 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 or sudden urges to urinate.
- problems with your liver.
- problems with your kidneys that requires dialysis. ACTOS is not recommended for use if you are on dialysis.
- bone fractures, usually in the hand, upper arm, or foot, have been seen in some women when taking ACTOS. Talk to your doctor for advice on how to keep your bones healthy.
- allergies to any other medicines, foods, preservatives or dyes.

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

Some women who do not have monthly periods and have not been through menopause may restart their periods when taking ACTOS. These women may be at increased risk of pregnancy.

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

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

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

It is recommended that you do not breastfeed while taking ACTOS, as it is not known whether ACTOS passes into breast milk.

Use in children

The use of ACTOS has not been studied in children.

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 ACTOS may interfere with each other and affect how they work. These include:

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

If you are taking any of these medicines you may need to adjust your dose or take different medicines. Your doctor will be able to provide information.

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

4. How do I use ACTOS?

How much to take

- Your doctor will tell you how many ACTOS 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.
- Your doctor may increase or decrease your dose in order to find the appropriate dose for your condition.
- Follow the instructions provided by your doctor as they might be different to the information in this leaflet.

When to take ACTOS

- Take ACTOS once a day at about the same time each day as advised by your doctor.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take ACTOS

- ACTOS tablets should be swallowed whole with a glass of water.
- ACTOS tables can be taken before or after food.

How long to take ACTOS for

- Continue using ACTOS until your doctor tells you to stop.
- This medicine helps control your condition but does not cure it. It is important to continue taking your medicine even if you feel well.

If you forget to use ACTOS

ACTOS should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

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

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

If you are not sure what to do ask your pharmacist for help. Your pharmacist can also provide some hints if you have trouble remembering.

If you use too much ACTOS

If you think that you have used too much ACTOS, 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 using ACTOS?

Things you should do

- **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 any other doctors, dentists and pharmacists who treat you that you are taking ACTOS.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ACTOS.
- 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 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.**

Call your doctor straight away if you:

- become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using ACTOS.

Things you should not do

- Do not stop using this 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.
- Do not take ACTOS 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.

Hypoglycaemia (low blood sugar)

- If you are taking ACTOS with other medications used to treat diabetes such as insulin or a sulfonylurea, you may be at risk for hypoglycaemia.

- Signs of hypoglycaemia may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger, numbness around the lips and fingers.
- **You should tell your doctor as soon as possible if you notice the above side effects.**

Heart failure

- If you are taking ACTOS in combination with insulin you may be at risk of heart failure which may show as localised swelling of the ankles, feet and hands (oedema) and/or fluid in the lungs (pulmonary oedema).
- Tell your doctor if you have gained weight since taking ACTOS. Weight gain can be associated with improved blood sugar control; however, it may also be a symptom of heart failure.
- **You should tell your doctor as soon as possible if you notice the above side effects.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ACTOS affects you.

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 experience any side effects which impact your ability to drive or operate machinery when taking this medicine, do not drive or do anything else that could be dangerous and contact your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store ACTOS in a cool dry place, out of direct light, where the temperature is below 25°C.
- Keep ACTOS in the original packaging, in a safe place, away from children.
- Keep your tablets in the aluminium blister pack until it is time to take them.

Follow the instructions on 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.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

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.

6. Are there any side effects?

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.

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

Some side effects may be related to the dose of ACTOS. 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 ACTOS you are taking.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Weight gain. • Signs of hypoglycaemia which may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger, numbness around the lips and fingers. • Macular oedema (an eye disorder that can affect vision). • Eye problems including blurred or double vision. • Increased risk of bone fracture in women. • Altered or impaired liver function. 	<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. • 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. • Heart failure which may show as localised swelling of the ankles, feet and hands (oedema) and/or fluid in the lungs (pulmonary oedema). 	<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>

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.

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7. Product details

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

What ACTOS contains

Active ingredient (main ingredient)	Pioglitazone (as hydrochloride)
Other ingredients (inactive ingredients)	Lactose Hyprolose Carmellose calcium Magnesium stearate
Potential allergens	Sugars as lactose

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

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

What ACTOS looks like

ACTOS is presented in aluminium blister packs containing 30 tablets.

- 15 mg ACTOS tablets are white to off-white, round, convex tablets, marked with a "15" on one side and "CLR" on the other (AUST R 76462).
- 30 mg ACTOS tablets are white to off-white, round flat tablets, marked with a "30" on one side and "CLR" on the other (AUST R 76463).
- 45 mg ACTOS tablets are white to off-white, round flat tablets, marked with a "45" on one side and "CLR" on the other (AUST R 76464).

Who distributes ACTOS

ACTOS is supplied in Australia by:

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia