

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 ONGLYZA?

ONGLYZA contains the active ingredient saxagliptin. ONGLYZA is used to lower blood sugar levels in patients with type 2 diabetes mellitus.

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

2. What should I know before I use ONGLYZA?

Do not use if you have ever had an allergic reaction to ONGLYZA 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 use ONGLYZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ONGLYZA 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 ONGLYZA?

- The usual dose of ONGLYZA is one 5 mg tablet once a day
- If you have kidney problems, your doctor may prescribe a lower daily dose of 2.5 mg.

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

5. What should I know while using ONGLYZA?

Things you should do	<ul style="list-style-type: none">• Tell any other doctors, dentists, and pharmacists who are treating you that you are taking ONGLYZA.• Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.
Things you should not do	<ul style="list-style-type: none">• Do not take ONGLYZA to treat any other complaints unless your doctor tells you do.• Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ONGLYZA affects you.• Make sure you know how you react to ONGLYZA before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool dry place where the temperature stays below 30°C.• Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

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

6. Are there any side effects?

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

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ONGLYZA. **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 ONGLYZA.**

Where to find information in this leaflet:

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

1. Why am I using ONGLYZA?

ONGLYZA contains the active ingredient saxagliptin.

ONGLYZA is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in patients with type 2 diabetes mellitus.

- ONGLYZA helps to improve the levels of insulin after a meal.
- ONGLYZA decreases the amount of sugar made by the body.
- ONGLYZA works when blood sugar is high, especially after a meal. This is when the body needs the greatest amount of help in lowering blood sugar. ONGLYZA also lowers blood sugar between meals.
- ONGLYZA by itself is unlikely to cause low blood sugar (hypoglycaemia) because it does not work when your blood sugar is low.

ONGLYZA is used to lower blood sugar levels in patients with type 2 diabetes mellitus. ONGLYZA is used in combination with certain other medicines (metformin, medicines such as rosiglitazone and pioglitazone, insulin, a sulfonylurea medicine such as glimepiride or glibenclamide or metformin plus a sulfonylurea or a SGLT2 inhibitor such as dapagliflozin) to help lower blood sugar levels. ONGLYZA is used when diet plus exercise and the single medicine do not provide adequate blood sugar level control.

Type 2 diabetes mellitus

Type 2 diabetes mellitus is a condition in which your body does not make enough insulin and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood and can lead to serious medical problems.

The main goal of treating diabetes is to lower your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes,

such as heart disease, kidney disease, blindness and amputation.

ONGLYZA is not addictive.

2. What should I know before I use ONGLYZA?

Warnings

Do not use ONGLYZA if:

- you are allergic to saxagliptin, the active ingredient in ONGLYZA or 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 or you may feel faint.
- you are allergic to any other DPP-4 inhibitor.
- you are lactose intolerant. ONGLYZA tablets contains lactose
- Do not take ONGLYZA after the use by (expiry) date printed on the pack.
- Do not take ONGLYZA if the packaging is torn or shows signs of tampering. If it is expired or is damaged, return it to your pharmacist for disposal.
- Do not use in children. There is not enough information on its effects in children.

Check with your doctor if you:

- if you have been prescribed this medicine for another reason.
- if you are not sure if you should start taking ONGLYZA.
- if you have any questions about why ONGLYZA has been prescribed for you.
- If you have allergies to any other medicines
- If you have allergies to any other substances such as food, dyes or preservatives

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.

ONGLYZA is not recommended for use during pregnancy.

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

ONGLYZA should not be used while breastfeeding or if planning to breastfeed.

Tell your doctor or pharmacist if you have, or have had, any medical conditions, especially the following:

- type 1 diabetes or a condition called diabetic ketoacidosis.
- Heart failure
- Kidney problems; your doctor will do some tests for kidney function at the start of treatment and regularly while you are on treatment.

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.

ONGLYZA can be taken with most other medicines.

If you have not told your doctor about any of these things, tell them before you take any ONGLYZA.

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

4. How do I use ONGLYZA?

How much to take / use

- The usual dose of ONGLYZA is one 5 mg tablet once a day.
- If you have kidney problems, your doctor may prescribe a lower daily dose of 2.5 mg.
- 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 pack ask your doctor or pharmacist for help.
- Continue taking the tablets for as long as your doctor tells you. Make sure you keep enough ONGLYZA to last over weekends and holidays.
- ONGLYZA helps control your condition, but does not cure it. Therefore you must take ONGLYZA every day.

When to take / use ONGLYZA

- ONGLYZA should be taken once a day, at approximately the same time each day.
- Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.
- ONGLYZA tablets can be taken with or without food.
- If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

How to take ONGLYZA

- Swallow your ONGLYZA tablets whole with a full glass of water.
- ONGLYZA tablets should not be split or cut.

If you forget to use ONGLYZA

If you miss your dose at the usual time **and 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.

If you use too much ONGLYZA

If you think that you have used too much ONGLYZA, 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 ONGLYZA?

Things you should do

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

Call your doctor straight away if you:

- If you are about to be started on any new medicines, inform that you are taking ONGLYZA
- Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.
- It is important to have regular check ups with your doctor or the diabetes centre.

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

If you need to have any medical tests while you are taking ONGLYZA, tell your doctor.

ONGLYZA may affect the results of some tests.

Visit your doctor regularly for check-ups.

Your doctor may want to perform blood tests to check your kidneys while you are taking ONGLYZA.

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

Things you should not do

- Do not stop using this medicine suddenly.
- Do not take ONGLYZA to treat any other complaints unless your doctor tells you to.

- Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.

Hypoglycemia

ONGLYZA does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines. Such as insulin or a sulphonylurea.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- hunger
- numbness around the lips and tongue

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Hyperglycaemia

If you notice the return of any of the signs of hyperglycaemia, contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less ONGLYZA than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery).

Your blood glucose may become difficult to control at these times.

Driving or using machines

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

ONGLYZA may cause dizziness in some people. Low blood sugar levels may also slow your reaction time and affect your ability to drive or operate machinery.

Make sure you know how you react to ONGLYZA before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your ONGLYZA tablets in the blister pack until it is time to take them.
- If you take ONGLYZA out of the blister pack it will not keep well.
- Keep it in a cool dry place where the temperature stays below 30°C.
- Heat and dampness can destroy some medicines.

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.

When to discard your medicine

If your doctor tells you to stop taking ONGLYZA or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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?

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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • headache 	Speak to your doctor if you

Less serious side effects	What to do
<ul style="list-style-type: none"> signs of an infection in the breathing passages including runny nose, sore throat and cough soreness in the back of the nose and throat and discomfort when swallowing difficulty breathing or tightness in the chest vomiting or diarrhoea stomach pain or discomfort swelling of hands, ankles or feet signs of urinary tract infection such as an urge to urinate frequently and in small amounts, and painful burning when passing urine rash feeling depressed or anxious joint pain signs of anaemia such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale back pain. 	<p>have any of these less serious side effects and they worry you or go to Accident and Emergency at your nearest hospital.</p>

Serious side effects

Serious side effects	What to do
<p>Hypoglycaemia:</p> <ul style="list-style-type: none"> Low blood sugar that persists despite administering sugar as described under WHILE YOU ARE TAKING ONGLYZA in this leaflet. Signs of hypoglycaemia may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, rapid heart beat, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers. Do not drive a car if you have signs of low blood sugar. <p>Allergic reaction:</p> <ul style="list-style-type: none"> severe allergic reaction (may include shortness of breath, wheezing or severe difficulty in breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives on the skin, hayfever, or you may feel faint). <p>Other serious side effects:</p>	<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> <p>These are very serious side effects. You may need urgent medical attention or hospitalisation.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> severe upper stomach pain, often with nausea and vomiting signs and symptoms of heart failure. Signs of heart failure may include, increasing shortness of breath, rapid increase in weight and swelling of the feet. develop blisters or the breakdown of your skin (erosion). These symptoms could be a sign of a skin reaction called bullous pemphigoid that can require treatment in a hospital. Your doctor may tell you to stop taking ONGLYZA. 	

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

Occasionally, ONGLYZA may be associated with changes in your blood. These can only be found when your doctor does tests from time to time to check your progress.

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

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

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 ONGLYZA contains

Active ingredient (main ingredient)	Saxagliptin 2.5 mg/5 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Lactose monohydrate microcrystalline cellulose croscarmellose sodium magnesium stearate polyvinyl alcohol macrogol 3350 titanium dioxide purified talc iron oxide red CI77491 (5 mg tablet only) iron oxide yellow CI77492 (2.5mg tablet only) Opacode Blue (printing ink)

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

What ONGLYZA looks like

ONGLYZA 2.5 mg tablet is a pale yellow to light yellow, round, film coated tablets with "2.5" printed on one side and "4214" printed on the other side, in blue ink (Aust R 211214).

ONGLYZA 5 mg tablet pink, biconvex, round, film coated tablets with "5" printed on one side and "4215" printed on the other side, in blue ink (AUST R 157907).

Who distributes ONGLYZA

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone:- 1800 805 342

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