

ONGLYZA®

Saxagliptin

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ONGLYZA 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 the medicine.

You may need to read it again.

What ONGLYZA is used for

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 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.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why ONGLYZA has been prescribed for you.

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

ONGLYZA is not addictive.

Before you take ONGLYZA

When you must not take it

Do not take ONGLYZA if you have an allergy to:

- **saxagliptin, the active ingredient in ONGLYZA or any of the other ingredients listed at the end of this leaflet.**
- **any other DPP-4 inhibitor.**

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.

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 has expired or is damaged, return it to your pharmacist for disposal.

ONGLYZA is not recommended for use in children.

There is not enough information on its effects in children.

If you are not sure whether you should start taking ONGLYZA, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have any allergies to:

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

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

- type 1 diabetes mellitus 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.

Tell your doctor if you are pregnant or intend to become pregnant.

ONGLYZA is not recommended for use during pregnancy

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

Tell your doctor if you are lactose intolerant.

ONGLYZA tablets contain lactose.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any 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.

How to take ONGLYZA

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.

How to take it

Swallow your ONGLYZA tablets whole with a full glass of water.

ONGLYZA tablets should not be split or cut.

How much to take

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

When to take it

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.

How long to take it

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.

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.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor or the Poisons Information Centre

(13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much ONGLYZA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ONGLYZA

Things you must do

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

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist 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.

HYPOGLYCAEMIA

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
- irritability, tearfulness or crying
- 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.

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.

Things you must not do

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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

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

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.

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

Tell your doctor if you notice any of the following and they worry you:

- headache
- 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.

These side effects are usually mild.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- signs of hypoglycaemia (low blood sugar) that persist 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.

- 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).
- 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.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking ONGLYZA

Storage

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.

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.

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 ONGLYZA or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What ONGLYZA looks like

ONGLYZA tablets are available in two strengths:

- 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.
- 2.5 mg tablet - 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.

ONGLYZA tablets are available in blister packs of 7 (sample pack) and 28 tablets.

Ingredients

Each ONGLYZA tablet contains saxagliptin 2.5 mg or 5 mg as the active ingredient.

Plus the following inactive ingredients:

- 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).

ONGLYZA tablets do not contain gluten or sucrose.

Sponsored by

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

Date of Preparation: January 2019

ONGLYZA Australian Registration Numbers:

5 mg - AUST R 157907

2.5 mg - AUST R 211214

ONGLYZA is a registered trademark of the AstraZeneca group of companies.

© AstraZeneca 2019

Doc ID-002350284 V10.0