PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ONGLYZA® 2,5; ONGLYZA ® 5 Film-coated Tablets

Saxagliptin

Contains sugar: lactose monohydrate 99 mg

Read all of this leaflet carefully before you start taking ONGLYZA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ONGLYZA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ONGLYZA is and what it is used for
2. What you need to know before you take ONGLYZA
3. How to take ONGLYZA
4. Possible side effects
5. How to store ONGLYZA
6. Contents of the pack and other information

1. What ONGLYZA is and what it is used for

ONGLYZA is a prescription medicine that belongs to a class of medicine called dipeptidyl peptidase-4 (DPP4) inhibitors.

ONGLYZA is used along with diet and exercise to lower blood sugar in people with type 2 diabetes. ONGLYZA may be taken alone or with certain other medicines to control blood sugar.

2. What you need to know before you take ONGLYZA

Do not take ONGLYZA:

- if you are hypersensitive (allergic) to saxagliptin or any of the other ingredients of ONGLYZA (listed in section 6) or to any other dipeptidyl peptidase-4 (DPP4) inhibitor medicine.
- if you have severe liver disease.
- if you have a previous history of pancreatitis (inflammation of the pancreas).

ONGLYZA should not be used to treat:

- people who have type 1 diabetes
- anyone with a history or risk of diabetic ketoacidosis (dangerously high levels of certain acids, known as ketones, in the blood or urine).

Warnings and precautions

Take special care with ONGLYZA:

While you are taking ONGLYZA tell your doctor, pharmacist or other healthcare professional about all of your medical conditions

- The sulfonylurea class of anti-hyperglycaemic agents is known to cause low blood sugar (hypoglycaemia) when used in combination with ONGLYZA, therefore your doctor might prescribe a lower dose sulfonylurea.
- If you have kidney problems, and importantly if you are 65 years or older with kidney problems, your doctor may prescribe a lower dose of ONGLYZA. Your doctor may perform blood tests on you from time to time to measure how well your kidneys are working.
- Tell your healthcare professional if you have had an allergic reaction to any other medicines that you take to control the amount of sugar in your blood.
- Tell your healthcare professional if you develop severe pain in your stomach which does not go away, as this may be a symptom of inflammation of the pancreas (pancreatitis).
- Talk to your doctor or pharmacist before taking ONGLYZA if you have ever had heart failure or you have other risk factors for developing heart failure such as problems with your kidneys and previous history of heart failure. Your doctor will advise you of the signs and symptoms of heart

failure. You should call your doctor, pharmacist or nurse immediately if you experience any of these symptoms. Symptoms can include, but are not limited to, increasing shortness of breath, rapid increase in weight and swelling of the feet (pedal oedema).

- Tell your healthcare professional if you develop severe joint pain.

Contact your doctor if you encounter blistering of the skin, as it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop ONGLYZA.

What else should I know about managing blood sugar while taking ONGLYZA?

- Monitor your blood sugar so you and your doctor can assess your progress.
- Stay on your prescribed diet and exercise programme while taking ONGLYZA.
- Talk to your doctor about how to prevent, recognise, and manage low blood sugar (hypoglycaemia), high blood sugar (hyperglycaemia), and other potential complications of diabetes.

Your doctor will monitor your diabetes with regular blood tests including your blood sugar levels and your haemoglobin A_1C.

Serious allergic reactions have been reported during use of ONGLYZA. Symptoms of a serious allergic reaction may include rash, raised red patches on your skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have these symptoms, stop taking ONGLYZA and contact your doctor, pharmacist or other healthcare professional right away.

Other medicines and ONGLYZA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

During periods of stress on the body, such as fever, trauma, infection, or surgery, contact your doctor right away as your medication needs may change.

ONGLYZA with food and drink

ONGLYZA can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Safety and efficacy have not been studied in pregnancy and breastfeeding.

You should not take ONGLYZA if you are pregnant.

If you are taking ONGLYZA, you should not breastfeed your baby.

Tell your doctor:

- If you are pregnant or plan to become pregnant, because ONGLYZA is not right for you. It is not known if ONGLYZA will harm your unborn baby. If you are pregnant, talk to your doctor about the best way to control your blood sugar while you are pregnant.
- If you are breastfeeding or plan to breastfeed. ONGLYZA may be passed in your milk to your baby. Talk to your doctor about the best way to feed your baby if you are taking ONGLYZA.

Driving and using machines

No studies have been performed on the ability to drive or to operate machinery, however, when driving or operating machines, it should be taken into account that dizziness has been reported with ONGLYZA.

ONGLYZA contains lactose

ONGLYZA contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ONGLYZA.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ONGLYZA

3. How to take ONGLYZA

Do not share medicines prescribed for you with any other person.

Always take ONGLYZA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- Take ONGLYZA 5 mg once daily.
- If you have a reduced kidney function, your doctor may prescribe a lower dose. This is one 2,5 mg tablet once a day.
- ONGLYZA can be taken with or without food
- Your doctor may prescribe ONGLYZA along with insulin or other medicines that lower blood sugar
- Try to take ONGLYZA at the same time each day.

If you take more ONGLYZA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ONGLYZA

If you miss a dose of ONGLYZA, take it as soon as you remember.
If you do not remember until it is almost time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of ONGLYZA to make up for a missed dose.

Talk to your pharmacist if you have questions about a missed dose.

4. Possible side effects

ONGLYZA can have side effects

Not all side effects reported for ONGLYZA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ONGLYZA, please consult your healthcare provider for advice.

If any of the following happens, stop taking ONLGYZA and tell your doctor immediately or go to the casualty department at your nearest hospital: swelling of the face, lips, mouth/tongue or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ONGLYZA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- upper respiratory infection
- urinary tract infection
- headache

Frequency not known side effects:

- Blistering of the skin (bullous pemphigoid)

Toxic epidermal necrolysis (TEN), Steven-Johnson syndrome, erythema multiforme, acute generalized exanthematous pustulosis (AGEP), erythroderma (generalized exfoliative dermatitis) have been reported in patients treated with DPP-4 inhibitors.

Cases of inflammation of the pancreas (pancreatitis) have been reported. Contact your healthcare professional right away if you have severe pain in your stomach which does not go away, as this may be a symptom of inflammation of the pancreas.

Cases of severe joint pain have been reported. Contact your healthcare professional right away if you have severe joint pain which does not go away.

ONGLYZA may also occasionally cause sinus infection, inflammation of the gastrointestinal tract, vomiting, abdominal pain, or stuffy/runny nose with sore throat.

Some patients have had a small reduction in the number of one type of white blood cells (lymphocytes) shown in a blood test when ONGLYZA was used alone or in combination.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ONGLYZA.

5. How to store ONGLYZA

Store all medicines out of reach of children.

Store at or below 25 °C

Store in the original container until required for use

Do not use ONGLYZA tablets after the expiry date stated on the container

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What ONGLYZA contains

The active substance is saxagliptin

Each ONGLYZA 2,5 mg tablet contains 2,5 mg saxagliptin free base

Each ONGLYZA 5 mg tablet contains 5 mg saxagliptin free base

The other ingredients are: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, iron oxide yellow and iron oxide red.

What ONLGYZA looks like and contents of the pack

ONGLYZA 2,5 mg is a pale yellow to light yellow, biconvex, round, film coated tablet, with “2.5” printed on one side and “4214” printed on the other side, in blue ink.
ONGLYZA 5 mg is a pink, biconvex, round, film coated tablet, with “5” printed on one side and “4215” printed on the other side, in blue ink.

Aluminium laminate/aluminium foil blister strips containing multiples of 10 tablets (in a 30’s pack size) packed in a cardboard carton.

Holder of Certificate of Registration

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ONGLYZA 2,5 mg tablets: 43/21.2/0608
ONGLYZA 5 mg tablets: 43/21.2/0609

Access to the corresponding Professional Information

To be allocated