

Read the Patient Information that comes with ONGLYZA before you start taking it and each time you get a refill. There may be new information. This patient leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment. If you have any questions about ONGLYZA, ask your healthcare provider.

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### What ONGLYZA is used for

- ONGLYZA is a prescription medicine used with diet and exercise to control high blood sugar (hyperglycemia) in adults with type 2 diabetes.

### How ONGLYZA works

- ONGLYZA lowers blood sugar by helping the body increase the level of insulin after meals.
- ONGLYZA is unlikely to cause your blood sugar to be lowered to a dangerous level (hypoglycemia) because it does not work well when your blood sugar is low. However, hypoglycemia may still occur with ONGLYZA. Your risk for getting hypoglycemia is higher if you take ONGLYZA with some other diabetes medicines, such as a sulfonylurea or insulin.
- ONGLYZA is not for people with type 1 diabetes.
- ONGLYZA is not for people with diabetic ketoacidosis (increased ketones in your blood or urine).

- It is not known if ONGLYZA is safe and effective in children younger than 18 years old.
- If you have had pancreatitis in the past, it is not known if you have a higher chance of getting pancreatitis while you take ONGLYZA.

### Before you use ONGLYZA

#### - When you must not use it

#### Do not take ONGLYZA if you:

- are allergic to any ingredients in ONGLYZA. See the end of this patient leaflet for a complete list of ingredients in ONGLYZA.

Symptoms of a serious allergic reaction to ONGLYZA may include:

- swelling of your face, lips, throat, and other areas on your skin
- difficulty with swallowing or breathing
- raised, red areas on your skin (hives)
- skin rash, itching, flaking, or peeling

If you have these symptoms, stop taking ONGLYZA and contact your healthcare provider right away.

#### - Before you start to use it

Tell your healthcare provider if you have ever had

- inflammation of your pancreas (pancreatitis)
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

It is not known if having these medical problems will make you more likely to get pancreatitis with ONGLYZA.

Stop taking ONGLYZA and contact your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or

without vomiting. These may be symptoms of pancreatitis.

### Tell your healthcare provider if you:

- have kidney problems
- are pregnant or plan to become pregnant. It is not known if ONGLYZA will harm your unborn baby. If you are pregnant, talk with your healthcare provider about the best way to control your blood sugar while you are pregnant.
- are breast-feeding or plan to breast-feed. ONGLYZA may be passed in your milk to your baby. Talk with your healthcare provider about the best way to feed your baby while you take ONGLYZA.

#### - Taking other medicines

**Tell your healthcare provider about all the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

ONGLYZA may affect the way other medicines work, and other medicines may affect how ONGLYZA works. Contact your healthcare provider if you will be starting or stopping certain other types of medications, such as antibiotics, or medicines that treat fungus or HIV/AIDS, because your dose of ONGLYZA might need to be changed.

### How to use ONGLYZA

#### - How much to use

- Take ONGLYZA by mouth one time each day exactly as directed by your healthcare provider. Do not change your dose without talking to your healthcare provider.

#### - When to use it

- Consult your healthcare provider on most suitable time to take ONGLYZA.

**- How long to use it**

- Take ONGLYZA as directed by your healthcare provider. Do not stop your dose without talking to your healthcare provider.

**- If you forget to use it**

- If you miss a dose of ONGLYZA, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time. Do not take two doses at the same time unless your healthcare provider tells you to do so. Talk to your healthcare provider if you have questions about a missed dose.

**- If you use too much (overdose)**

- If you take too much ONGLYZA, call your healthcare provider, or go to the nearest hospital emergency room right away.

**While you are using it**

**- Things you must do**

- Follow your healthcare provider's instructions for treating blood sugar that is too low (hypoglycemia). Talk to your healthcare provider if low blood sugar is a problem for you.
- ONGLYZA can be taken with or without food.

**- Things you must not do**

- Do not split or cut ONGLYZA tablets.

**- Things to be careful of**

- During periods of stress on the body, such as:
  - fever
  - trauma
  - infection
  - surgeryContact your healthcare provider right away as your medication needs may change.
- Your healthcare provider should test your blood to measure how well your kidneys are working

before and during your treatment with ONGLYZA. You may need a lower dose of ONGLYZA if your kidneys are not working well.

**Side effects**

**Serious side effects can happen to people taking ONGLYZA**, including inflammation of the pancreas (pancreatitis) which may be severe and lead to death.

Certain medical problems make you more likely to get pancreatitis.

- **Allergic (hypersensitivity) reactions**, such as:
  - swelling of your face, lips, throat, and other areas on your skin
  - difficulty with swallowing or breathing
    - raised, red areas on your skin (hives)
    - skin rash, itching, flaking, or peelingIf you have these symptoms, stop taking ONGLYZA and contact your healthcare provider right away.

Common side effects of ONGLYZA include:

- upper respiratory tract infection
- urinary tract infection
- headache

**Low blood sugar (hypoglycemia)** may become worse in people who already take another medication to treat diabetes, such as sulfonylureas or insulin. Tell your healthcare provider if you take other diabetes medicines. If you have symptoms of low blood sugar, you should check your blood sugar and treat if low, then call your healthcare provider. Symptoms of low blood sugar include:

- shaking
- sweating
- rapid heartbeat
- change in vision
- hunger
- headache

- change in mood

**Swelling or fluid retention** in your hands, feet, or ankles (peripheral edema) may become worse in people who also take a thiazolidinedione to treat diabetes. If you do not know whether you are already on this type of medication, ask your healthcare provider.

These are not all of the possible side effects of ONGLYZA. Tell your healthcare provider if you have any side effects that bother you or that do not go away. For more information, ask your healthcare provider.

Call your healthcare provider for medical advice about side effects.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling TEL: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

**General information about the use of ONGLYZA**

Medicines are sometimes prescribed for conditions that are not mentioned in patient leaflets. Do not use ONGLYZA for a condition for which it was not prescribed. Do not give ONGLYZA to other people, even if they have the same symptoms you have. It may harm them.

This patient leaflet summarizes the most important information about ONGLYZA. If you would like to know more information about ONGLYZA, talk with your healthcare provider. You can ask your healthcare provider for additional information about ONGLYZA that is written for healthcare professionals. “

**What is type 2 diabetes?**

Type 2 diabetes 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. This can lead to serious medical problems.

The main goal of treating diabetes is to lower your blood sugar so that it is as close to normal as possible.

High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

**Storage and Disposal of ONGLYZA**

**Storage**

Store Onglyza below 30°C.

Keep ONGLYZA and all medicines out of the reach of children.

**Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

**- What it looks like**

ONGLYZA (saxagliptin) 2.5 mg tablets are pale yellow to light yellow, biconvex, round, film-coated tablets with “2.5” printed on one side and “4214” printed on the reverse side, in blue ink.

ONGLYZA (saxagliptin) 5 mg tablets are pink, biconvex, round, film-coated tablets with “5” printed on one side and “4215” printed on the reverse side, in blue ink.

**- Ingredients**

Active ingredient: saxagliptin

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, and iron oxides.

**- MAL number**

2.5mg: MAL20102019AR

5mg: MAL20102020AR

**Manufacturer**

Manufactured by Bristol-Myers Squibb Company,  
4601 Highway 62 East, Mount Vernon, Indiana 47620, USA

and

Packaged by Bristol-Myers Squibb S.r.l. 03012 Anagni, Italy for AstraZeneca.

**Product Registration Holder**

AstraZeneca Sdn. Bhd.  
Level 12, Surian Tower,  
1 Jalan PJU 7/3,  
Mutiara Damansara,  
47810 P. J., Selangor.

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