

# ONGLYZA<sup>®</sup>

## Saxagliptin 2.5 mg and 5 mg film-coated tablets

### CONSUMER MEDICINE INFORMATION

#### What is in this leaflet

This leaflet answers some of the common questions people ask about **Onglyza**. It does not contain all the information that is known about **Onglyza**. 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 pharmacist or doctor.**

**Keep this leaflet with the medicine.** You may need to read it again.

#### What Onglyza is used for

**Onglyza** contains the active substance saxagliptin, which belongs to a group of medicines called 'oral anti-diabetics'. They work by helping to control the level of sugar in your blood.

**Onglyza** is used for adult patients aged 18 years and older with 'type 2 diabetes', if the disease cannot be adequately controlled with one oral anti-diabetic medicine, diet and exercise. **Onglyza** is used together with another anti-diabetic medicine.

It is important to keep following the advice about diet and exercise that you have been given by your doctor or nurse.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

This medicine is only available with a doctor's prescription. **Onglyza** is not addictive

#### Before you use Onglyza

##### **When you must not use it**

Do not take **Onglyza**

- if you are allergic (hypersensitive) to saxagliptin or any of the other ingredients of **Onglyza** (see Product Description).
- if you have had a serious allergic (hypersensitive) reaction to any other similar medications that you take to control your blood sugar.

Symptoms of a serious allergic reaction may include.

- Rash
- Raised red patches on your skin (hives)
- Swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.

If you have any of these symptoms, stop taking **Onglyza** and **see your doctor immediately**.

Do not use **Onglyza** if you are pregnant or intend to become pregnant. Ask your doctor about effective methods of contraception. If you become pregnant, stop taking **Onglyza** as soon as you find out and see your doctor immediately.

Do not use **Onglyza** if you are breastfeeding. It is not known if your baby can take in **Onglyza** from breast milk if you are breast feeding.

Do not take **Onglyza** after the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well. Do not take **Onglyza** if the packaging is torn or shows signs of tampering.

**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 this medicine.

### **Before you start to use it**

Check with your doctor or pharmacist before taking **Onglyza** if you:

- are taking insulin. **Onglyza** should not be used in place of insulin.
- have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting). **Onglyza** should not be used to treat these conditions,
- have or have had a disease of the pancreas,
- are taking insulin or an anti-diabetic medicine known as 'sulphonylurea', your doctor may want to reduce your dose of insulin or the sulphonylurea when you take it together with **Onglyza** in order to avoid low blood sugar,
- have had allergic reactions to any other medicines that you take to control the amount of sugar in your blood,
- have a condition that reduces your defence against infections, such as a disease like AIDS, or from medicines that you might take after an organ transplant;
- suffer from heart failure or you have other risk factors for developing heart failure such as problems with your kidneys. 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),
- have reduced kidney function, your doctor will decide if you will need to take a lower dose of **Onglyza**. If you are having haemodialysis then **Onglyza** is not recommended for you,
- have moderate or severe liver problems. If you have severe liver problems, then **Onglyza** is not recommended for you.

If you have not told your pharmacist or doctor about any of the above, tell them before you take **Onglyza**.

Diabetic skin lesions are a common complication of diabetes. Rash has been seen with **Onglyza** and with certain anti-diabetic medicines in the same class as **Onglyza**. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse.

**Onglyza** is not recommended for children and adolescents under 18 years. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

### **Taking other medicines**

**You must tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription. In particular, you should tell your doctor if you are using medicines listed below:**

- Carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
- Dexamethasone – a steroid medicine. This may be used to treat inflammation in different body parts and organs.
- Rifampicin. This is an antibiotic used to treat infections such as tuberculosis.
- Ketoconazole. This may be used to treat fungal infections.

- Diltiazem. This is a medicine used to lower blood pressure.

If you have not told your pharmacist or doctor about any of the above, tell them before you take **Onglyza**. Your doctor or pharmacist will consider whether **Onglyza** should be used together with any of these medicines. These medicines may affect the way **Onglyza** works.

### How to use Onglyza

**Always take Onglyza exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.**

#### **How much to take**

The usual dose of **Onglyza** is one 5 mg tablet once a day.

If you have reduced kidney function, your doctor may prescribe a lower dose. This is one 2.5 mg tablet once a day.

Your doctor will prescribe **Onglyza** together with insulin or other another anti-diabetic medicine. If applicable, remember to take these other medicines as directed by your doctor to achieve the best results for your health.

#### **When to take it**

The tablet can be taken at any time of the day, however try to take your tablet at the same time each day. This will help you to remember to take it.

#### **How to take it**

Swallow the tablet whole with some water. You can take the tablet with or without food. **Tablets must not be split or cut.**

#### **How long to take it**

**Keep taking Onglyza until your doctor tells you to stop.** This is to help keep your blood sugar under control.

#### **If you forget to take it**

**If you forget to take a dose of Onglyza, take it as soon as you remember.** However, if it is nearly time for the next dose, skip the missed dose and wait until your next dose is due and take it as normal. **Do not double the dose to make up for the one you missed. Never take two doses on the same day.**

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

### While you are using Onglyza

#### **Things you must do**

Tell all doctors, dentists and pharmacists who treat you that you have recently taken **Onglyza**.

If you are about to be started on any new medicine, remind your pharmacist or doctor that you have recently taken **Onglyza**.

#### **Things you must not do**

Do not give **Onglyza** to anyone else, even if they have the same condition as you.

Do not stop taking **Onglyza** unless you have discussed it with your doctor.

#### **Things to be careful of**

**Be careful driving a car or operating machinery until you know Onglyza affects you.** If you feel dizzy while taking **Onglyza**, do not drive or use any tools or machines. Hypoglycaemia may affect your ability to drive and use machines or work with safe foothold and there is a risk of hypoglycaemia when

taking this medicine in combination with medicines known to cause hypoglycaemia such as insulin and sulphonylureas.

### In case of overdose

#### ***If you take too much (overdose)***

Please telephone your doctor or the National Poisons Centre Phone: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much **Onglyza**, even if there are no signs of discomfort or poisoning.

### 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 these side effects. **Ask your doctor or pharmacist to answer any questions you may have.**

**You should stop taking Onglyza and see your doctor immediately if you experience the following symptoms of low blood sugar (hypoglycaemia):**

- trembling,
- sweating,
- anxiety,
- blurred vision,
- tingling lips,
- paleness,
- mood change,
- vagueness or confusion.

Symptoms of a serious allergic reaction may include:

- Rash
  - Raised red patches on your skin (hives)
  - 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 call your doctor or nurse right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

You should stop taking **Onglyza** and contact a doctor immediately if you notice any of the following serious side effects:

- severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).

You should call your doctor if you experience the following side effect:

- Severe joint pain.

Some patients have had the following side effects while taking **Onglyza** and **metformin**:

- infection of the upper chest or lungs,
- infection of the urinary tract,
- inflamed stomach or gut usually caused by an infection (gastroenteritis),

- infection of the sinuses with a feeling of pain and fullness behind your cheeks and eyes (sinusitis),
- inflamed nose or throat (nasopharyngitis) (signs of this may include a cold or a sore throat),
- headache,
- muscle pain (myalgia),
- vomiting,
- inflammation of the stomach (gastritis),
- stomach ache
- indigestion (dyspepsia),
- joint pain (arthralgia),
- difficulties in getting or maintaining an erection (erectile dysfunction).

Some patients have had the following side effects while taking **Onglyza** and a **sulphonylurea**:

- low blood sugar (hypoglycaemia),
- infection of the upper chest or lungs,
- infection of the urinary tract,
- inflamed stomach or gut usually caused by an infection (gastroenteritis),
- infection of the sinuses with a feeling of pain and fullness behind your cheeks and eyes (sinusitis),
- headache,
- stomach ache
- vomiting,
- tiredness,
- abnormal lipid (fatty acids) levels (dyslipidaemia, hypertriglyceridaemia).

Some patients have had the following side effects while taking **Onglyza** and a **thiazolidinedione**:

- infection of the upper chest or lungs,
- infection of the urinary tract,
- inflamed stomach or gut usually caused by an infection (gastroenteritis),
- infection of the upper sinuses with a feeling of pain and fullness behind your cheeks and eyes (sinusitis),
- headache,
- stomach ache
- vomiting,
- swelling of the hands, ankles or feet (peripheral oedema).

Some patients have had the following side effects while taking **Onglyza** and **metformin** and a **sulphonylurea**:

- dizziness,
- tiredness,
- stomach ache,
- flatulence.

Some patients have experienced constipation when taking **Onglyza**.

Some patients have had a small reduction in the number of one type of white blood cells (lymphocytes) shown in a blood test when taking **Onglyza**.

**Tell your doctor if you notice any of the above and they worry you. If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

**Important:** This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Onglyza**. Tell your pharmacist if you notice anything else that is making you feel unwell or bothering you.

### After using 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 your **Onglyza** in a cool dry place where the temperature stays below 30°C. Do not leave **Onglyza** in the car on hot days. Keep your **Onglyza** 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. Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

#### **Disposal**

Ask your pharmacist what to do with **Onglyza** after you have used it, or you find that the expiry date has passed.

### Product Description

#### ***What Onglyza looks like***

**Onglyza** 2.5 mg film-coated tablets are pale yellow to light yellow, biconvex, round. They have “2.5” printed on one side and “4214” printed on the other side, in blue ink.

**Onglyza** 5 mg film-coated tablets are pink, biconvex, round. They have “5” printed on one side and “4215” printed on the other side, in blue ink.

#### ***Ingredients:***

**Onglyza** contains 2.5 mg or 5 mg of saxagliptin (as hydrochloride).

The other ingredients are:

Tablet core: lactose monohydrate, cellulose microcrystalline (E460i), croscarmellose sodium (E468), magnesium stearate.

Film coating: polyvinyl alcohol, macrogol/3350, titanium dioxide (E171) and talc (E553b). **Onglyza** 5 mg tablets also contain iron oxide red (E172). **Onglyza** 2.5 mg tablets also contain iron oxide yellow (E172).

Printing ink: shellac, indigo carmine aluminium lake (E132).

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