Package leaflet: Information for the patient

Onglyza 2.5 mg film-coated tablets
Onglyza 5 mg film-coated tablets
Saxagliptin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Onglyza is and what it 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 alone or together with insulin or other anti-diabetic medicines.

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

2. What you need to know before you take Onglyza

Do not take Onglyza
- if you are allergic to saxagliptin or any of the other ingredients of this medicine (listed in section 6).
- if you have had a serious allergic reaction to any other similar medicines that you take to control your blood sugar. See section 4.

Warnings and precautions:
Talk to your doctor or pharmacist before taking Onglyza:
- if you are taking insulin. Onglyza should not be used in place of insulin;
- if you 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;
- if you have or have had a disease of the pancreas;
- if you 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 either of them together with Onglyza in order to avoid low blood sugar;

- if you 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;
- if you 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);
- if you have reduced kidney function, your doctor will decide if you need to take a lower dose of Onglyza. If you are having haemodialysis then Onglyza is not recommended for you;
- if you have moderate or severe liver problems. If you have severe liver problems, then Onglyza is not recommended for you.

Diabetic skin lesions are a common complication of diabetes. Rash has been seen with Onglyza (see section 4) 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.

Children and adolescents
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.

Other medicines and Onglyza
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, you should tell your doctor if you are using medicines containing any of the following active substances:
- 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.

Pregnancy and breast-feeding
Talk to your doctor before you take Onglyza if you are pregnant or plan to become pregnant. You should not use Onglyza if you are pregnant.

Talk to your doctor if you want to breast-feed while taking this medicine. It is not known if Onglyza passes into human breast milk. You should not take this medicine if you are breast-feeding or plan to breast-feed.

Driving and using machines
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.

Onglyza contains lactose
The tablets contain 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.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially ‘sodium-free’.

3. How to take Onglyza

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

The recommended dose of Onglyza is 5 mg 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 may prescribe Onglyza alone or together with insulin or other anti-diabetic medicines. If applicable remember to take these other medicines as directed by your doctor to achieve the best results for your health.

How to take Onglyza
The tablets must not be split or cut. Swallow the tablet whole with some water. You can take the tablet with or without food. 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.

If you take more Onglyza than you should
If you take more tablets than you should, talk to a doctor straight away.

If you forget to take Onglyza
- If you forget to take a dose of Onglyza, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention:
You should stop taking Onglyza and see your doctor immediately if you experience the following symptoms of low blood sugar: trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change, vagueness or confusion (hypoglycaemia). Seen very commonly (may affect more than 1 in 10 people).

Symptoms of a serious allergic reaction (seen rarely, may affect up to 1 in 1,000 people) 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:
- Common (may affect 1 to 10 users in 100): 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 and indigestion (dyspepsia).
- Uncommon (may affect 1 to 10 users in 1,000): joint pain (arthralgia) and difficulties in getting or maintaining an erection (erectile dysfunction).

Some patients have had the following side effects while taking Onglyza and a sulphonylurea:
- Very common: low blood sugar (hypoglycaemia)
- Common: 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 and vomiting.
- Uncommon: tiredness, abnormal lipid (fatty acids) levels (dyslipidaemia, hypertriglyceridaemia).

Some patients have had the following side effects while taking Onglyza and a thiazolidinedione:
- Common: 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, vomiting, stomach ache and 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:
- Common: dizziness, tiredness, stomach ache and flatulence.

Some patients have had the following additional side effects while taking Onglyza alone:
- Common: dizziness, diarrhoea and stomach ache.

Some patients have experienced constipation at an unknown frequency (cannot be determined from the available data) when Onglyza was used alone or in combination.

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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Onglyza

Keep this medicine out of the sight and reach of children.

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.

This medicine does not require any special storage conditions.

Do not use this medicine if the package is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Onglyza contains
- The active substance is saxagliptin.
  Each film-coated tablet contains 2.5 mg saxagliptin (as hydrochloride).
  Each film-coated tablet contains 5 mg 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); talc (E553b) and Onglyza 5 mg tablets contain iron oxide red (E172). Onglyza 2.5 mg tablets contain iron oxide yellow (E172).
- Printing ink: shellac; indigo carmine aluminium lake (E132).

What Onglyza looks like and contents of the pack
- 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.
- 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.
- Tablets available in aluminium foil blisters
- 2.5 mg tablets are available in pack sizes of 14, 28, or 98 film-coated tablets in non-perforated calendar blisters and 30x1 or 90x1 film-coated tablets in perforated unit dose blisters
- 5 mg tablets are available in pack sizes of 14, 28, 56, or 98 film-coated tablets in non-perforated blisters, 14, 28, 56, or 98 film-coated tablets in non-perforated calendar blisters and 30x1 or 90x1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder
AstraZeneca AB
SE-151 85 Södertälje
Sweden

Manufacturer
AstraZeneca UK Limited
Silk Road Business Park
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United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
AstraZeneca UK Ltd
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Ireland
AstraZeneca Pharmaceuticals (Ireland) DAC
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Malta
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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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