

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Onglyza™ 2.5 mg

Film-coated tablets

Onglyza™ 5 mg

Film-coated tablets

Each tablet contains:

saxagliptin (as HCl) 2.5 mg

saxagliptin (as HCl) 5 mg

For inactive ingredients, please see section 6 – Further Information.

Read this leaflet carefully in its entirety before using the medicine.

Keep this leaflet; you may need it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

This medicine is not intended for children and adolescents under the age of 18 years.

1. WHAT IS THE MEDICINE INTENDED FOR?

Onglyza is intended to balance blood sugar levels in adult patients (from the age of 18 and above) with type 2 diabetes:

- in combination with diet and exercise.
- in combination with insulin or other oral anti-diabetic medicine, in cases in which the diabetes is inadequately controlled when using one anti-diabetic medicine.

- as an initial treatment in combination with metformin, diet and exercise.

Do not use in patients with end-stage renal disease (ESRD)

Therapeutic group:

Dipeptidyl peptidase (DPP 4) inhibitor

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
- you have had a severe allergic reaction (hypersensitivity) to Onglyza or to any other similar medicine intended to balance blood sugar levels. See section 4 – Side Effects.
- you are pregnant.
- you are breastfeeding.

Special warnings regarding use of Onglyza

Talk to your doctor before taking Onglyza if:

- you are taking insulin. Onglyza should not be used in place of insulin
- you have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, drastic weight loss, nausea and vomiting). Onglyza should not be used for these conditions.
- you have, or have ever had, a pancreatic disease.
- you are taking insulin or another anti-diabetic medicine of the sulphonylurea group together with Onglyza; the doctor may reduce the dosage of insulin and/or sulphonylurea to prevent low blood sugar levels.
- you have a disease that reduces the activity of the immune system, such as Acquired immune deficiency syndrome (AIDS), or if you are taking medi-

cines that cause a reduction in immune system activity, for example, medicines taken after organ transplant.

- you suffer from heart failure.
- you have ever had heart failure, or if you have risk factors for heart failure, such as problems with your kidneys. Your doctor will explain the signs of heart failure. Immediately refer to a doctor, pharmacist or nurse if you experience any of these signs. The signs can include (but are not limited to) – escalating shortness of breath, rapid weight gain and swelling of the feet (edema in the feet and ankles, pedal oedema).
- you have reduced kidney function; your doctor will decide if you need to take a lower dosage of Onglyza. If you are having hemodialysis – use of Onglyza is not recommended.
- you have moderate or severe liver function impairment. If you have severe liver function impairment, use of Onglyza is not recommended.
- Skin lesions are a common complication among diabetes patients. Rash is an effect observed following treatment with Onglyza (see section 4 – Side effects) and other anti-diabetic medicines from the same Class as Onglyza. Follow the nurse or doctor's recommendations regarding treatment of the skin and legs. 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.

! Children and adolescents

Onglyza is not recommended for children and adolescents under 18 years.

There is no data regarding safety and efficacy of use of this medicine in children and adolescents.

! Drug Interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

- Carbamazepine, phenobarbital or phenytoin (for seizures, long lasting pain that does not pass),

- Dexamethasone (a steroid for treatment of inflammations),
- Rifampicin (antibiotic to treat infections such as tuberculosis),
- Ketoconazole (to treat fungal infections),
- Diltiazem (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 the medicine 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 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 when taking Onglyza, do not drive a car, operate dangerous machinery or engage in any activity that requires alertness. Hypoglycemia may affect your ability to drive and to operate dangerous machinery. There is risk of hypoglycemia when taking Onglyza with preparations known to cause hypoglycemia, such as insulin and sulphonylurea.

Important information regarding some of the ingredients of the medicine

The tablets contain lactose (milk sugar). If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.

Onglyza 2.5 mg and Onglyza 5 mg tablets: each tablet contains 99 mg lactose monohydrate.

This medicine contains less than 23 mg sodium per tablet, that is to say it is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use in accordance with the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

- The dosage and treatment regimen will be determined by the doctor only.
- Do not exceed the recommended dose.
- Onglyza will be given to you in combination with another anti-diabetic medicine. Take Onglyza and the other medicine precisely as instructed by your doctor.
- If you have kidney function impairment, the doctor may prescribe a lower dosage of Onglyza; this dosage is 2.5 mg Onglyza, once a day.
- When your body is in a state of stress, such as fever, trauma (e.g., car accident), infection or surgery, you may need to change the dosage of the medicine. Inform the doctor if any of these conditions apply to you.

Instructions for use:

- Do not halve or cut the tablets. There is no data regarding crushing the tablets. Swallow the tablets whole with water.
- Onglyza can be taken with or without food.
- Onglyza can be taken at any time during the day, but try to take the tablets at the same time every day.

If you accidentally take too high a dosage or if a child has accidentally swallowed the medicine, immediately refer to the doctor or proceed to the hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember; but if you remembered close to the time for the next dose, do not take the previous dose that you missed. Never take two doses together.

Adhere to the treatment regimen as recommended by the doctor.

How can you contribute to the success of the treatment?

Complete the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Onglyza may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment with Onglyza and immediately refer to a doctor if you experience the following effects that are due to low blood sugar levels **very common effects** (affect more than 1 in 10 patients):

- trembling,
- sweating,
- anxiety,
- blurred vision,
- tingling lips,
- paleness,
- mood change,
- vagueness or confusion (hypoglycemia),

Symptoms of a severe allergic reaction (seen rarely, at a frequency of 1-10 in 10,000 users) can include:

- rash

- red patches (lumps) on the skin (hives)
- swelling of the face, lips, tongue, and throat that can cause breathing or swallowing difficulties.

If you have these signs, stop taking Onglyza and immediately refer to the attending doctor or nurse. The doctor may prescribe a medicine for you to treat the allergic reaction and a different medicine for your diabetes.

Stop taking Onglyza and contact the doctor immediately if you notice the following severe side effect:

- Severe and persistent abdominal pain that can radiate to the back, as well as nausea and vomiting; this can be a sign of pancreatitis.

Refer to the doctor if you suffer from the following side effect:

- Severe joint pain

Possible side effects when taking Onglyza with metformin:

Common side effects (effects that appear in 1-10 in 100 patients):

- upper respiratory tract infection,
- urinary tract infection,
- inflammation of the stomach or intestines usually caused by an infection (gastroenteritis),
- sinusitis with a feeling of pain and fullness behind your cheeks and eyes,
- inflamed nose or throat (a cold or sore throat),
- headache,
- muscle pain,
- vomiting,
- inflammation of the stomach (gastritis),
- stomachache and indigestion.

Uncommon side effects (effects that appear in 1-10 in 1000 patients):

- joint pain,
- difficulty in getting or maintaining an erection.

Possible side effects while taking Onglyza with a sulphonylurea:

Very common side effects (effects that appear in more than 1 in 10 patients):

- low blood sugar level (hypoglycemia).

Common side effects (effects that appear in 1-10 in 100 patients):

- upper respiratory tract infection,
- urinary tract infection,
- inflammation of the stomach or intestines usually caused by an infection (gastroenteritis),
- sinusitis with a feeling of pain and fullness behind your cheeks and eyes,
- headache,
- stomachache and vomiting.

Uncommon side effects (effects that appear in 1-10 in 1000 patients):

- tiredness,
- abnormal blood fat (lipid) levels (dyslipidemia, hypertriglyceridemia).

Possible side effects while taking Onglyza with a thiazolidinedione:

Common side effects (effects that appear in 1-10 in 100 patients):

- upper respiratory tract infection,

- urinary tract infection,
- inflammation of the stomach or intestines usually caused by an infection (gastroenteritis),
- sinusitis with a feeling of pain and fullness behind your cheeks and eyes,
- headache,
- vomiting,
- stomachache,
- swelling of the hands, ankles or legs (edema).

Other possible side effects while taking Onglyza alone:

Common side effects (effects that appear in 1-10 in 100 patients):

- dizziness
- diarrhea
- stomachache

Possible side effects while taking Onglyza alone or in combination with other medicines:

Side effects with unknown frequency (the frequency cannot be determined yet):

- constipation
- blistering of the skin (bullous pemphigoid)

In some patients, a small reduction in the number of white blood cells, lymphocytes, has been shown in blood tests. Observed in blood tests when using Onglyza alone or in combination with another medicine.

If one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Report side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/bottle/carton/label. The expiry date refers to the last day of that month.
- Even when stored as per the packaging/storage recommendations, medicines may be kept for a limited period only. Do not store different medicines in the same package.
- Store below 30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Contents of the **Onglyza 2.5 mg** and **Onglyza 5 mg** tablet:

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

Onglyza 2.5 mg tablet coating:

Polyvinyl alcohol, macrogol 3350, titanium dioxide (E171), talc (E553b), shellac, indigo carmine aluminium lake (E132), iron oxide yellow (E172).

Onglyza 5 mg tablet coating:

Polyvinyl alcohol, macrogol 3350, titanium dioxide (E171), talc (E553b), shellac, indigo carmine aluminium lake (E132), iron oxide red (E172).

What the medicine looks like:

Onglyza 5 mg tablets are film-coated, round, biconvex, and pink, with "5" imprinted on one side and "4215" imprinted on the other side, in blue ink.

Onglyza 2.5 mg tablets are film-coated, round, biconvex, and yellow to light yellow, with "2.5" imprinted on one side and "4214" imprinted on the other side, in blue ink.

License holder and importer: AstraZeneca (Israel) Ltd., P.O. Box 1455, Hod Hasharon 4524075.

Manufacturer: AstraZeneca Pharmaceuticals LP, Mount Vernon, Indiana, USA.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Onglyza 2.5 mg: 146 47 33404

Onglyza 5 mg: 144 74 33080