Package leaflet: Information for the patient

Saxagliptine Sandoz® 2,5 mg, filmomhulde tabletten
Saxagliptine Sandoz® 5 mg, filmomhulde tabletten

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What {[nationally completed name]} is and what it is used for

{[Nationally completed name]} contains the active substance saxagliptin, which belongs to a group of medicines called 'oral antidiabetics'. They work by helping to control the level of sugar in your blood.

{[Nationally completed name]} is used for adult patients aged 18 years and older with type 2 diabetes, if the disease cannot be adequately controlled with one oral antidiabetic medicine, diet and exercise. {[Nationally completed name]} is used alone or together with insulin or other antidiabetic 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 {[nationally completed name]}

Do not take {[nationally completed name]}
- 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 {[nationally completed name]}:
- if you are taking insulin
  {[Nationally completed name]} 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) {[Nationally completed name]} 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 antidiabetic 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 {[nationally completed name]} 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 {[nationally completed name]}
  If you are having haemodialysis then {[nationally completed name]} is not recommended for you.
- if you have moderate or severe liver problems
  If you have severe liver problems, then {[nationally completed name]} is not recommended for you.

Diabetic skin lesions are a common complication of diabetes. Rash has been seen with {[nationally completed name]} (see section 4) and with certain antidiabetic medicines in the same class as {[nationally completed name]}. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. 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 taking {[nationally completed name]}.

Children and adolescents
{[nationally completed name]} is not recommended for children and adolescents under 18 years.

Other medicines and {[nationally completed name]}

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 (medicines used to control fits (seizures) or chronic pain)
- dexamethasone (a steroid medicine used to treat inflammation in different body parts and organs)
- rifampicin (medicine used to treat infections such as tuberculosis)
- ketoconazole (medicine used to treat fungal infections)
- diltiazem (medicine used to lower blood pressure)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use {[nationally completed name]} if you are pregnant.

It is not known if {[nationally completed name]} 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 {[nationally completed name]}, 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.

{[Nationally completed name]} contains lactose and sodium
The film-coated 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.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take {[nationally completed name]}

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 {[nationally completed name]} 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. For this dose, a 2.5 mg tablet strength is available.

Your doctor may prescribe {[nationally completed name]} alone or together with insulin or other oral antidiabetic 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 {[nationally completed name]}
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 {[nationally completed name]} than you should
If you take more tablets than you should, talk to a doctor straight away.

If you forget to take {[nationally completed name]}
- If you forget to take a dose of {[nationally completed name]}, 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 {[nationally completed name]}
Keep taking {[nationally completed name]} 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 {[nationally completed name]} 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 {[nationally completed name]} 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 {[nationally completed name]} 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 {[nationally completed name]} and metformin:
- **common (may affect up to 1 in 10 people):** 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 up to 1 in 100 people):** joint pain (arthralgia) and difficulties in getting or maintaining an erection (erectile dysfunction)

Some patients have had the following side effects while taking {[nationally completed name]} and a sulphonylurea:
- **very common (may affect more than 1 in 10 people):** low blood sugar (hypoglycaemia)
- **common (may affect up to 1 in 10 people):** 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 (may affect up to 1 in 100 people):** tiredness, abnormal lipid (fatty acids) levels (dyslipidaemia, hypertriglyceridaemia)

Some patients have had the following side effects while taking {[nationally completed name]} and a thiazolidinedione:
- **common (may affect up to 1 in 10 people):** 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 {[nationally completed name]} and metformin and a sulphonylurea:
- **common (may affect up to 1 in 10 people):** dizziness, tiredness, stomach ache and flatulence

Some patients have had the following additional side effects while taking {[nationally completed name]} alone:
- **common (may affect up to 1 in 10 people):** dizziness, diarrhoea and stomach ache

Some patients have had the following side effects while taking {[nationally completed name]} alone or in combination:

- **not known (frequency cannot be estimated from the available data):** constipation, blistering of the skin (bullous pemphigoid)

Some patients have had a small reduction in the number of one type of white blood cells (lymphocytes) shown in a blood test when {[nationally completed name]} 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 via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {[nationally completed name]}

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.

Store below 30°C.
Store in the original package in order to protect from moisture.

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 protect the environment.

6. Contents of the pack and other information

What {[nationally completed name]} contains

2.5 mg film-coated tablets
- The active substance is saxagliptin. Each film-coated tablet contains 2.5 mg saxagliptin (as hydrochloride).
- The other ingredients are:
  - tablet core: lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, magnesium stearate
  - film-coating: hypromellose 2910, macrogol 6000, lactose anhydrous, titanium dioxide (E 171), iron oxide yellow (E 172)

  See section 2 "{[Nationally completed name]} contains lactose and sodium".

5 mg film-coated tablets
- The active substance is saxagliptin. Each film-coated tablet contains 5 mg saxagliptin (as hydrochloride).
- The other ingredients are:

- tablet core: lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, magnesium stearate
- film-coating: hypromellose 2910, macrogol 6000, lactose anhydrous, titanium dioxide (E 171), iron oxide red (E 172)

See section 2 "{[Nationally completed name]} contains lactose and sodium".

What {[nationally completed name]} looks like and contents of the pack

2.5 mg film-coated tablets
Light yellow, round, biconvex film coated tablet with "SG" embossed on one side and "2.5" on the other side.
Diameter 8.1 - 8.8 mm; thickness 3.9 - 5.5 mm

5 mg film-coated tablets
Light pink, round, biconvex film coated tablet with "SG" embossed on one side and "5.0" on the other side.
Diameter 8.1 - 8.8 mm; thickness 3.9 - 5.5 mm

The film-coated tablets are packed in OPA/Alu/PVC//Alu/PVC blisters and inserted in a carton.

Pack sizes:
2.5 mg film-coated tablets
Blister pack: 14, 28, 30, 60, 90, 98
Unit dose blister pack: 30x1, 90x1

5 mg film-coated tablets
Blister pack: 14, 28, 30, 56, 60, 90, 98
Unit dose blister pack: 30x1, 56x1, 90x1

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V.
Hospitaaldreef 29
1315 RC Almere
Nederland

Fabrikant
Lek Pharmaceuticals, d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Lek Pharmaceuticals, d.d.

Trimlini 2D
9220 Lendava
Slovenië

In het register ingeschreven onder:
Saxagliptine Sandoz 2,5 mg, filmomhulde tabletten - RVG 123112
Saxagliptine Sandoz 5 mg, filmomhulde tabletten - RVG 123113

Dit middel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Saxagliptine Sandoz 2,5 mg, filmomhulde tabletten
	Saxagliptine Sandoz 5 mg, filmomhulde tabletten
België	Saxagliptin Sandoz 2,5 mg filmomhulde tabletten
	Saxagliptin Sandoz 5 mg filmomhulde tabletten
Duitsland	Saxagliptin Hexal 2,5 mg Filmtabletten
	Saxagliptin Hexal 5 mg Filmtabletten
Estland	Saxagliptin Sandoz
Frankrijk	SAXAGLIPTINE SANDOZ 2.5 mg, comprimé pelliculé
	SAXAGLIPTINE SANDOZ 5 mg, comprimé pelliculé
Slovenië	Saksagliptin Sandoz 2,5 mg filmsko obložene tablete
	Saksagliptin Sandoz 5 mg filmsko obložene tablete
Verenigd Koninkrijk	Saxagliptin Sandoz 2.5 mg Film Coated Tablets
	Saxagliptin Sandoz 5 mg Film Coated Tablets

Deze bijsluiter is voor het laatst goedgekeurd in december 2025.