PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Saxagliptin Sandoz 2.5 mg film-coated tablets
Saxagliptin Sandoz 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 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 Saxagliptin Sandoz film-coated tablets are and what they are used for
2. What you need to know before you take Saxagliptin Sandoz film-coated tablets
3. How to take Saxagliptin Sandoz film-coated tablets
4. Possible side effects
5. How to store Saxagliptin Sandoz film-coated tablets
6. Contents of the pack and other information

SANDOZ

1 What Saxagliptin Sandoz film-coated tablets are and what they are used for

Saxagliptin Sandoz film-coated tablets 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.

Saxagliptin 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. Saxagliptin 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 Saxagliptin Sandoz film-coated tablets

Do not take Saxagliptin
- 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 Saxagliptin:
- if you are taking insulin

Saxagliptin 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)

Saxagliptin 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 Saxagliptin 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 Saxagliptin

If you are having haemodialysis then Saxagliptin is not recommended for you.
- if you have moderate or severe liver problems

If you have severe liver problems, then Saxagliptin is not recommended for you.

Diabetic skin lesions are a common complication of diabetes. Rash has been seen with Saxagliptin (see section 4) and with certain anti-diabetic medicines in the same class as Saxagliptin. 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 Saxagliptin.

Children and adolescents
Saxagliptin is not recommended for children and adolescents under 18 years.

Other medicines and Saxagliptin Sandoz film-coated tablets

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 Saxagliptin if you are pregnant.

It is not known if Saxagliptin 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 Saxagliptin, 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.

Saxagliptin 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 Saxagliptin Sandoz film-coated tablets

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 Saxagliptin 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 Saxagliptin alone or together with insulin or other oral 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 Saxagliptin Sandoz film-coated tablets
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 Saxagliptin than you should
If you take more tablets than you should, talk to a doctor straight away.

If you forget to take Saxagliptin
- If you forget to take a dose of Saxagliptin, 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 Saxagliptin
Keep taking Saxagliptin 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 Saxagliptin 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,

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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 Saxagliptin 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 Saxagliptin 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 Saxagliptin 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 Saxagliptin 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 Saxagliptin 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 Saxagliptin 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 Saxagliptin 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 Saxagliptin 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 Saxagliptin 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 Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Saxagliptin Sandoz film-coated tablets

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 Saxagliptin Sandoz film-coated tablets contain

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 "Saxagliptin 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 "Saxagliptin contains lactose and sodium".

What Saxagliptin Sandoz film-coated tablets look 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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sandoz Limited
Park View, Riverside Way
Watchmoor Park
Camberley, Surrey
GU15 3YL
United Kingdom

Manufacturer
Lek Pharmaceuticals d.d,
Verovškova 57,
1526 Ljubljana,
Slovenia

Lek Pharmaceuticals d.d,
Trimlini 2D,
9220 Lendava,
Slovenia

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