PACKAGE LEAFLET

Package leaflet: Information for the user

Linagliptine Sandoz® 5 mg, filmomhulde tabletten

linagliptin

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 [Nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance linagliptin which belongs to a group of medicines called “oral anti-diabetics”. Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

[Nationally completed name] is used for ‘type 2 diabetes’ in adults, if the disease cannot be adequately controlled with one oral anti-diabetic medicine (metformin or sulphonylureas) or diet and exercise alone. [Nationally completed name] may be used together with other anti-diabetic medicines e.g. metformin, sulphonylureas (e.g. glimepiride, glipizide), empagliflozin, or insulin.

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 linagliptin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking [Nationally completed name] 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.
- are taking an anti-diabetic medicine known as a 'sulphonylurea'(e.g. glimepiride, glipizide), your doctor may want to reduce your dose of sulphonylurea when you take it together with [Nationally completed name] in order to avoid your blood sugar going too low.
- have had allergic reactions to any other medicines that you take to control the amount of sugar in your blood.
- have or have had a disease of the pancreas.

If you have symptoms of acute pancreatitis, like persistent, severe stomach ache (abdominal pain), you should consult your doctor.

If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop [Nationally completed name].

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse.

Children and adolescents
[Nationally completed name] is not recommended for children and adolescents under 18 years. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 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. These may be used to control fits (seizures) or chronic pain.
- Rifampicin. This is an antibiotic used to treat infections such as tuberculosis.

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.

It is unknown if [Nationally completed name] is harmful to the unborn child. Therefore, it is preferable to avoid using [Nationally completed name] if you are pregnant.
It is not known if [Nationally completed name] passes into human breast milk. A decision must be made by your doctor whether to discontinue breast-feeding or to discontinue/abstain from [Nationally completed name] therapy.

Driving and using machines
[Nationally completed name] has no or negligible influence on the ability to drive and use machines.

Taking [Nationally completed name] in combination with medicines called sulphonylureas and/or insulin can cause too low blood sugar levels (hypoglycaemia), which may affect your ability to drive and use machines or work without safe foothold. However, more frequent blood glucose testing might be recommended to minimise the risk for hypoglycaemia, especially when [Nationally completed name] is combined with sulphonylurea and/or insulin.

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.
You can take [Nationally completed name] with or without food.
Your doctor may prescribe [Nationally completed name] together with another oral anti-diabetic medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

If you take more [Nationally completed name] than you should
If you take more [Nationally completed name] than you should, talk to a doctor immediately.

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]
Do not stop taking [Nationally completed name] without first consulting your doctor. Your blood sugar levels may increase when you stop taking [Nationally completed name].

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

4. Possible side effects

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

<u>Some symptoms need immediate medical attention</u>
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 or confusion (hypoglycaemia). Hypoglycaemia (frequency: very common, may affect more than 1 in 10 people) is an identified side effect when [Nationally completed name] is taken together with metformin and a sulphonylurea.

Some patients have experienced allergic reactions (hypersensitivity; frequency uncommon, may affect up to 1 in 100 people) while taking [Nationally completed name] alone or in combination with other medicinal products for the treatment of diabetes, which may be serious, including wheezing and shortness of breath (bronchial hyperreactivity; frequency not known, frequency cannot be estimated from the available data). Some patients experienced rash (frequency uncommon), hives (urticaria; frequency rare, may affect up to 1 in 1000 people), and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema; frequency rare). If you experience any of the signs of illness mentioned above, stop taking [Nationally completed name] and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have experienced inflammation of the pancreas (pancreatitis; frequency rare, may affect up to 1 in 1000 people) while taking [Nationally completed name] alone or in combination with other medicinal products for the treatment of diabetes.
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).

Some patients have had the following side effects while taking [Nationally completed name] alone or in combination with other medicinal products for the treatment of diabetes:

- Common: level of lipase in the blood increased.
- Uncommon: inflamed nose or throat (nasopharyngitis), cough, constipation (in combination with insulin), level of amylase in the blood increased.
- Rare: blistering of skin (bullous pemphigoid).

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.

[HU/H/0904-0905/001/DC:]
Do not use this medicine after the expiry date which is stated on the blister and the carton and bottle after EXP. The expiry date refers to the last day of that month.

[HU/H/0906/001/DC:]
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 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
- The active substance is linagliptin.
  Each film-coated tablet (tablet) contains 5 mg of linagliptin.
- The other ingredients are:
  Tablet core: mannitol (E421), crospovidone (E1202), hypromellose (E464), silica, colloidal anhydrous (E551) and magnesium stearate (E470b).
  Film coating: hypromellose (E464), titanium dioxide (E171), talc (E553b), macrogol (E1521) and red iron oxide (E172).

What [Nationally completed name] looks like and contents of the pack
[Nationally completed name] <5 mg> <film-coated tablets> are light pink, round, biconvex, film-coated tablets measuring approximately 8 mm in diameter and debossed with '5' on one side.

[HU/H/0904-0905/001/DC:]
[Nationally completed name] is available in aluminium foil blisters. The pack sizes are 10, 14, 28, 30, 60, 90, 100 and 120 tablets.

[Nationally completed name] is available in aluminium foil perforated unit dose blisters. The pack sizes are 10 x 1, 14 x 1, 28 x 1, 30 x 1, 60 x 1, 90 x 1, 100 x 1 and 120 x 1 tablets.

[Nationally completed name] is also available in a plastic bottle with a child resistant plastic cap and packets containing silica gel desiccant. The pack size is 120 tablets.

[HU/H/0906/001/DC:]
[Nationally completed name] is available in aluminium foil blisters. The pack size is 28 tablets.

[Nationally completed name] is available in aluminium foil perforated unit dose blisters. The pack size is 28 x 1 tablets.

Not all pack sizes may be marketed.

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

Vergunninghouder
Sandoz B.V.
Hospitaaldreef 29
1315 RC Almere
Nederland

Fabrikanten
PharOS MT Ltd
HF62X, Hal Far Industrial Estate
Birzebbugia BBG3000
Malta

Lek Pharmaceuticals d.d.
Verovskova Ulica 57
1526, Ljubljana
Slovenië

Pharos Pharmaceutical Oriented Services Ltd.
Lesvou Street End, Thesi Loggos,
Industrial Zone Metamorfossi, 144 52
Griekenland

In het register ingeschreven onder:
RVG 131536 - Linagliptine Sandoz 5 mg, filmomhulde tabletten

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Oostenrijk	Linagliptin Sandoz 5 mg - Filmtabletten
België	Linagliptin Sandoz 5 mg filmomhulde tabletten
Tsjechië	Linagliptin Sandoz
Denemarken	Linagliptin Sandoz
Spanje	Linagliptina Sandoz 5 mg comprimidos recubiertos con película EFG
Finland	Linagliptin Sandoz 5 mg tabletti kalvopäällysteinen
Hongarije	Linagliptin Sandoz 5 mg filmtabletta
Ierland	Linagliptin Rowex 5 mg film-coated tablets
Nederland	Linagliptine Sandoz 5 mg, filmomhulde tabletten
Noorwegen	Linagliptin Sandoz
Portugal	Linagliptina Sandoz
Zweden	Linagliptin Sandoz
Slowakije	Linagliptin Sandoz 5 mg

Deze bijsluiter is voor het laatst goedgekeurd in november 2024