Package leaflet: Information for the user

Sitagliptin 25 mg film-coated tablet
Sitagliptin 50 mg film-coated tablet
Sitagliptin 100 mg film-coated tablet

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 symptoms 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 Sitagliptin is and what it is used for
2. What you need to know before you take Sitagliptin
3. How to take Sitagliptin
4. Possible side-effects
5. How to store Sitagliptin
6. Contents of the pack and other information

1. WHAT SITAGLIPTIN IS AND WHAT IT IS USED FOR

The name of your medicine is Sitagliptin film-coated tablets called Sitagliptin throughout this leaflet.

What is Sitagliptin and what is it used for?

The name of your medicine is Sitagliptin film-coated tablets called Sitagliptin throughout this leaflet.

Sitagliptin contains the active substance sitagliptin hydrochloride which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

This medicine helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

Your doctor has prescribed this medicine to help lower your blood sugar, which is too high because of your type 2 diabetes. This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which you may already be taking for your diabetes together with a food and exercise plan.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar.
When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SITAGLIPTIN

Do not take Sitagliptin:
- if you are allergic to sitagliptin or any of the other ingredients of this medicine (listed in section 6)

Warnings and Precautions:

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Sitagliptin (see section 4).

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 Sitagliptin

Tell your doctor if you have or have had:
- a disease of the pancreas (such as pancreatitis)
- gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis (see section 4).
- type 1 diabetes
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- any past or present kidney problems
- an allergic reaction to Sitagliptin (see section 4)

This medicine is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when this medicine is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medicine.

Children and adolescents

Children and adolescents below 18 years should not use this medicine. 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 Sitagliptin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor if you are taking digoxin (a medicine used to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if taking with Sitagliptin.

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 take this medicine during pregnancy.
It is not known if this medicine passes into breast milk. You should not take this medicine if you are breast-feeding or plan to breast-feed.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported, which may affect your ability to drive or use machines. Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

Other ingredients

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
Sitagliptin 25 mg film-coated tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE SITAGLIPTIN

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

The usual recommended dose is:
- one 100 mg film-coated tablet
- once a day
- by mouth

If you have kidney problems, your doctor may prescribe lower doses (such as 25 mg or 50 mg). You can take this medicine with or without food and drink.

Your doctor may prescribe this medicine alone or with certain other medicines that lower blood sugar.

Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise recommended by your doctor while taking Sitagliptin.

If you take more Sitagliptin than you should

If you take more than the prescribed dosage of this medicine, contact your doctor immediately.

If you forget to take Sitagliptin

If you forget a dose, take it as soon as you remember it. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Sitagliptin

Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first.
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.

STOP taking Sitagliptin 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 with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis)

If you have a serious allergic reaction (frequency not known), including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine 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 the following side effects after adding sitagliptin to metformin:
Common (may affect up to 1 in 10 people): low blood sugar, nausea, flatulence, vomiting
Uncommon (may affect up to 1 in 100 people): stomach ache, diarrhoea, constipation, drowsiness

Some patients have experienced the different types of stomach discomfort when starting the combination of sitagliptin and metformin together (frequency is common)

Some patients have experienced the following side effects while taking sitagliptin in combination with a sulphonylurea and metformin:
Very common (may affect more than 1 in 10 people): low blood sugar
Common: constipation

Some patients have experienced the following side effects while taking sitagliptin and pioglitazone:
Common: flatulence, swelling of the hands or legs

Some patients have experienced the following side effects while taking sitagliptin in combination with pioglitazone and metformin:
Common: swelling of the hands and legs

Some patients have experienced the following side effects while taking sitagliptin in combination with insulin (with or without metformin):
Common: flu
Uncommon: dry mouth

Some patients have experienced the following side effects while taking sitagliptin alone in clinical studies or during post-approval use alone and/or with other diabetes medicines
Common: low blood sugar, headache, upper respiratory infection, stuffy or runny nose and sore throat, osteoarthritis, arm or leg pain
Uncommon: dizziness, constipation, itching
Rare (may affect up to 1 in 1,000 people): reduced number of platelets
Not known: kidney problems (sometimes requiring dialysis), vomiting, joint pain, muscle pain, back pain, interstitial lung disease, bullous pemphigoid (a type of skin blister).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at 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 SITAGLIPTIN
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 medicinal product 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 Sitagliptin contains
The active substance is sitagliptin. Each film-coated tablet contains sitagliptin hydrochloride equivalent to 25mg, 50 mg and 100 mg of sitagliptin.

The other ingredients are microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate, magnesium stearate.

Sitagliptin 25 mg film coating contains lactose monohydrate, hypromellose, titanium dioxide (E171) triacetin, red iron oxide (E172).

Sitagliptin 50 mg and 100 mg film coating contains polyvinyl alcohol, hypromellose, macrogol, talc titanium dioxide (E171), red and yellow iron oxide (E172).

What Sitagliptin looks like and contents of the pack
Sitagliptin 25 mg film-coated tablet are pink, round, biconvex film-coated tablets approximately 6 mm diameter, debossed with “LC” on one side and plain on the other.

Sitagliptin 50 mg film-coated tablet are orange, round, biconvex film-coated tablets approximately 8 mm diameter, debossed with “C” on one side and plain on the other.

Sitagliptin 100 mg film-coated tablet are beige, round, biconvex film-coated tablets approximately 9.8 mm diameter, debossed with “L” on one side and plain on the other

The tablets are packed in blisters containing 14, 28, 30, 56 tablets and bottles of 100 tablets.
Not all packs sizes may be marketed.

Marketing Authorisation Holder and manufacturer
Marketing Authorisation Holder
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer
Laboratorios Liconsa, S.A., Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo, 19200 Azuqueca de Henares, Guadalajara, Spain

Other formats
To request a copy of this leaflet in braille, large print or audio please call 01484 848164.

This leaflet was revised in December 2024.

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908109-01