**Bijsluiter: informatie voor de patiënt**

**Sitagliptine/Metformine HCl Sandoz® 50mg/850 mg, filmomhulde tabletten**
**Sitagliptine/Metformine HCl Sandoz® 50mg/1000 mg, filmomhulde tabletten**

sitagliptine/metforminehydrochloride

**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 [Product name] is and what it is used for

[Product name] contains two different medicines called sitagliptin and metformin.
- sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors)
- metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called ‘type 2 diabetes mellitus’. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by your body.

Along with diet and exercise, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

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 [Product name]

**Do not take [Product name]:**
- if you are allergic to sitagliptin or metformin or any of the other ingredients of this medicine (listed in section 6).

- if you have severely reduced kidney function
- if you have uncontrolled diabetes, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you have a severe infection or are dehydrated
- if you are going to have an X-ray where you will be injected with a dye. You will need to stop taking [Product name] at the time of the X-ray and for 2 or more days after as directed by your doctor, depending on how your kidneys are working
- if you have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties
- if you have liver problems
- if you drink alcohol to excess (either every day or only from time to time)
- if you are breast-feeding

Do not take [Product name] if any of the above apply to you and talk with your doctor about other ways of managing your diabetes. If you are not sure, talk to your doctor, pharmacist or nurse before taking [Product name].

**Warnings and precautions**
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving [Product name] (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 [Product name].

**Risk of lactic acidosis**
[Product name] may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions.

**Stop taking [Product name] for a short time if you have a condition that may be associated with dehydration** (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

**Stop taking [Product name] and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis**, as this condition may lead to coma.
Symptoms of lactic acidosis include:
- vomiting
- stomachache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor or pharmacist before taking [Product name]:

- if you have or have had a disease of the pancreas (such as pancreatitis)
- if you have or have had 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)
- if you have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- if you have or have had an allergic reaction to sitagliptin, metformin, or [Product name] (see section 4)
- if you are taking a sulphonylurea or insulin, diabetes medicines, together with [Product name], as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin

If you need to have major surgery, you must stop taking [Product name] during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with [Product name].

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking [Product name].

During treatment with [Product name], your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

**Children and adolescents**
Children and adolescents below 18 years should not use this medicine. 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 [Product name]**
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking [Product name] before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with [Product name].

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of [Product name]. It is especially important to mention the following:

- medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- specific medicines for the treatment of bronchial asthma (β-sympathomimetics)
- iodinated contrast agents or alcohol-containing medicines
- certain medicines used to treat stomach problems such as cimetidine
- ranolazine, a medicine used to treat angina
- dolutegravir, a medicine used to treat HIV infection
- vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer)
- digoxin (to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if taking with [Product name].

**[Product name] with alcohol**
Avoid excessive alcohol intake while taking [Product name] since this may increase the risk of lactic acidosis (see section "Warnings and precautions").

**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 or if you are breast-feeding. See section 2, **Do not take [Product name].**

**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 with sitagliptin, 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.

**[Product name] contains sodium**
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 [Product name]

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

- Take one tablet:
  - twice daily by mouth
  - with meals to lower your chance of an upset stomach.

- Your doctor may need to increase your dose to control your blood sugar.

- If you have reduced kidney function, your doctor may prescribe a lower dose.

You should continue the diet recommended by your doctor during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day.

This medicine alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When this medicine is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

**If you take more [Product name] than you should**
If you take more than the prescribed dosage of this medicine, contact your doctor immediately. Go to the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing (see section "Warnings and precautions").

**If you forget to take [Product name]**
If you miss a dose, take it as soon as you remember. 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 of this medicine.

**If you stop taking [Product name]**
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 stop taking [Product name], your blood sugar may rise again.

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 [Product 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 with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).

[Product name] may cause a very rare (may affect up to 1 in 10,000 people), but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens, you must **stop taking [Product name] and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.
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 taking metformin have experienced the following side effects after starting sitagliptin:
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 diarrhoea, nausea, flatulence, constipation, stomach ache or vomiting when starting the combination of sitagliptin and metformin together (frequency is common).

Some patients have experienced the following side effects while taking this medicine with a sulphonylurea such as glimepiride:
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 this medicine in combination with pioglitazone:
Common: swelling of the hands or legs

Some patients have experienced the following side effects while taking this medicine in combination with insulin:
Very common: low blood sugar

Uncommon: dry mouth, headache

Some patients have experienced the following side effects during clinical studies while taking sitagliptin alone (one of the medicines in [Product name]) or during post-approval use of [Product name] or sitagliptin alone 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: reduced number of platelets
Frequency not known: kidney problems (sometimes requiring dialysis), vomiting, joint pain, muscle pain, back pain, interstitial lung disease, bullous pemphigoid (a type of skin blister)

Some patients have experienced the following side effects while taking metformin alone:
Very common: nausea, vomiting, diarrhoea, stomach ache and loss of appetite. These symptoms may happen when you start taking metformin and usually go away
Common: a metallic taste
Very rare: decreased vitamin B12 levels, hepatitis (a problem with your liver), hives, redness of the skin (rash) or itching

**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 [Product 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 the month.

Opaque PVC/PE/PVDC -aluminum blisters
Do not store above 30 °C.

OPA/Alu/PVC- aluminium blisters
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 [Product name] contains**

- The active substances are sitagliptin and metformin.

*[Product name] 50 mg/850 mg film-coated tablets*
Each film-coated tablet (tablet) contains sitagliptin hydrochloride monohydrate equivalent to 50 mg of sitagliptin and 850 mg of metformin hydrochloride.

*[Product name] 50 mg/1 000 mg film-coated tablets*
Each film-coated tablet (tablet) contains sitagliptin hydrochloride monohydrate equivalent to 50 mg of sitagliptin and 1 000 mg of metformin hydrochloride.

- The other ingredients are: In the tablet core: povidone, sodium laurilsulfate, cellulose microcrystalline, magnesium stearate.

In addition, the film coating contains:
50 mg/850 mg film-coated tablets
Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide red (E172), and iron oxide black (E172).

50mg / 1 000mg film-coated tablets:
Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide red (E172), and iron oxide yellow (E172).

**What [Product name] looks like and contents of the pack**

[Product name] 50 mg/850 mg film-coated tablets
Pink, capsule-shaped, biconvex, film-coated tablet with "585" engraved on one side and break line on the other side.

[Product name] 50 mg/1 000 mg film-coated tablets
Red, capsule-shaped, biconvex, film-coated tablet with "5100" engraved on one side and break line on the other side.

Opaque PVC/PE/PVDC -aluminum or OPA/Alu/PVC- Aluminium, perforated or not perforated blisters. Packs of 14, 28, 56, 100, 112, 168, 196 film-coated tablets, multi-packs containing 196 (2 packs of 98) and 168 (2 packs of 84) film-coated tablets.

Not all pack sizes may be marketed.

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

Vergunninghouder:
Sandoz B.V.
Veluwezoom 22
1327 AH Almere
Nederland

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

Rontis Hellas Medical and Pharmaceutical Products S.A
P.O Box 3012 Larisa Industrial Area
41004 Larisa
Griekenland

Lek Pharmaceuticals d.d.
Verovškova Ulica 57
1526 Ljubljana
Slovenië

**In het register ingeschreven onder:**
Sitagliptine/Metformine Sandoz 50mg/850 mg, filmomhulde tabletten - RVG 127562
Sitagliptine/Metformine Sandoz 50mg/1000 mg, filmomhulde tabletten - RVG 127563

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

| | |
|---|---|
| Nederland: | Sitagliptine/Metformine HCl Sandoz 50mg/850 mg, 50mg/1000 mg, filmomhulde tabletten |
| Duitsland: | Sitagliptin Metformin HEXAL 50mg/850 mg Filmtabletten |

**Deze bijsluiter is voor het laatst goedgekeurd in december 2022.**