

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Sitagliptin Combo Sandoz® 50/850 mg

Film-coated tablets

Composition:

Each film-coated tablet contains: sitagliptin (as hydrochloride monohydrate) 50 mg metformin hydrochloride 850 mg

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems that their medical condition is similar to yours.

1. What is this medicine intended for?

Sitagliptin Combo Sandoz, along with a recommended diet and exercise program is indicated to lower blood sugar levels in adult patients with type 2 diabetes.

Therapeutic group: Sitagliptin: DPP-4 enzyme inhibitor; Metformin: biguanide.

Sitagliptin Combo Sandoz is a tablet that contains 2 prescription medicines, sitagliptin and metformin, which lower blood sugar. Sitagliptin and metformin work together to control blood sugar levels in patients with type 2 diabetes mellitus, in whom this combination is appropriate.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to any of the active ingredients in **Sitagliptin Combo Sandoz** or to any of the other ingredients in this medicine (see section 6). Symptoms of a serious allergic reaction to **Sitagliptin Combo Sandoz** may include rash, raised red patches on your skin (hives), or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.
- You have type 1 diabetes mellitus.
- You have severely impaired renal function (your doctor will determine the level of impairment in your renal function).
- You have diabetic ketoacidosis (elevated levels of ketones in your blood or urine: diabetes complication which includes high blood sugar levels, rapid weight loss, nausea or vomiting).

Special warnings about using this medicine

Before starting treatment with Sitagliptin Combo Sandoz, tell your doctor about all of your medical problems, including if:

- You have or have had inflammation of your pancreas (pancreatitis). If you have had pancreatitis in the past, it is not known if you have a higher chance of getting pancreatitis while you take **Sitagliptin Combo Sandoz** (see section 4 'Side effects').
- You have kidney problems.
- You have liver problems.
- You have or have had gallstones.
- You have high blood triglyceride levels.
- You have heart failure.
- You drink alcohol very often, or drink a lot of alcohol in a short time, or you are or were addicted to alcohol.
- You are going to get an injection of dye or contrast agents for an x-ray. You may need to stop taking **Sitagliptin Combo Sandoz** for a short time. Consult your doctor about when to stop taking **Sitagliptin Combo Sandoz** and when you should start taking **Sitagliptin Combo Sandoz** again (see section 4 'Side effects').
- You have low levels of vitamin B₁₂ in your blood.
- You are pregnant or plan to become pregnant (see 'Pregnancy, breastfeeding and fertility').
- You are breastfeeding or plan to breastfeed (see 'Pregnancy, breastfeeding and fertility').
- You are a woman who has not gone through menopause (premenopausal) who does not have periods regularly or at all (see 'Pregnancy, breastfeeding and fertility').

Stop taking **Sitagliptin Combo Sandoz** and contact your doctor right away if you have pain in your stomach area that is severe and will not go away. You may feel the pain going from your abdomen through to your back. The pain may appear with or without vomiting. These may be symptoms of pancreatitis.

Tests and follow-up

Check your blood sugar as instructed by your doctor.

Your doctor will monitor your diabetes with regular blood tests, including checking your blood sugar levels and your glycated hemoglobin (A1C). Your doctor may order blood tests to check your vitamin B₁₂ levels.

Children and adolescents

Sitagliptin Combo Sandoz is not intended for administration to children under 18 years of age.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Particularly if you are taking:

- Topiramate (for the treatment of convulsions and migraines)
- Acetazolamide (for the treatment of edema, glaucoma and mountain sickness)
- Dolutegravir (for the treatment of HIV infection)
- Cimetidine (for the treatment of ulcers)
- Ranolazine
- Vandetanib

Sitagliptin Combo Sandoz may affect the way other medicines work and other medicines may affect how **Sitagliptin Combo Sandoz** works. Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

Using this medicine and food

Take **Sitagliptin Combo Sandoz** with meals to help to lower your chance of having an upset stomach.

Pregnancy, breastfeeding and fertility

- If you are pregnant or plan to become pregnant: It is not known if **Sitagliptin Combo Sandoz** will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar levels during pregnancy.
- If you are breastfeeding or plan to breastfeed: It is not known if **Sitagliptin Combo Sandoz** will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking **Sitagliptin Combo Sandoz**.
- If you are a woman who has not gone through menopause (premenopausal) who does not have periods regularly or at all: **Sitagliptin Combo Sandoz** can cause the release of an egg from an ovary in a woman (ovulation). This can increase your chance of getting pregnant. Tell your doctor right away if you become pregnant while taking **Sitagliptin Combo Sandoz**.

Important information about some of this medicine's ingredients

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

3. How should you use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

Your doctor will tell you how many **Sitagliptin Combo Sandoz** tablets to take and when you should take them.

Do not exceed the recommended dose.

Your doctor may change your dose of **Sitagliptin Combo Sandoz** if needed.

Take **Sitagliptin Combo Sandoz** with meals to help to lower your chance of an upset stomach.

Your doctor may tell you to take **Sitagliptin Combo Sandoz** along with certain other diabetes medicines. Low blood sugar (hypoglycemia) can happen more often when **Sitagliptin Combo Sandoz** is taken with certain other diabetes medicines (see section 4 'Side effects').

There is no information about crushing, splitting, or chewing these tablets. If you cannot swallow **Sitagliptin Combo Sandoz** tablets whole, tell your doctor. If you have reduced kidney function, your doctor may prescribe a lower dose.

- If you take too much **Sitagliptin Combo Sandoz**, call your doctor right away.
- If you have taken an overdose or if a child has accidentally swallowed some medicine, go immediately to a hospital emergency room and bring the medicine package with you.

• 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 dosing schedule. Do not take 2 doses of **Sitagliptin Combo Sandoz** at the same time.

You may need to stop taking **Sitagliptin Combo Sandoz** for a short time. Call your doctor for instructions if you:

- are dehydrated (have lost too much body fluid). Dehydration can occur if you are sick with severe vomiting, diarrhea or fever, or if you drink much less fluid than usual.
- plan to have surgery.
- are going to get an injection of dye or contrast agent for an x-ray. (See 'Special warnings about using this medicine' and section 4 'Side effects').

When your body is under different types of stress such as fever, trauma (such as a car accident), infection or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these conditions, and follow your doctor's instructions.

Stay on your prescribed diet and exercise program while taking **Sitagliptin Combo Sandoz**.

Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and problems you have because of your diabetes.

Continue to take **Sitagliptin Combo Sandoz** as long as your doctor tells you to.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, ask your doctor or pharmacist.

4. Side effects

Like with all medicines, using **Sitagliptin Combo Sandoz** may cause side effects in some users.

Do not be alarmed by this list of side effects. You may not experience any of them.

Sitagliptin Combo Sandoz may cause serious side effects, including:

Lactic acidosis. Metformin, one of the medicines in Sitagliptin Combo Sandoz, can cause a rare (may affect up to 1 in 10,000 users), but serious condition called lactic acidosis (a buildup of an acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.

Stop taking **Sitagliptin Combo Sandoz** and talk to your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing

• you feel sleepy or drowsy

- you have stomach pains, nausea or vomiting

Most people who have had lactic acidosis with metformin have other things that, when combined with the metformin, led to lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance of developing lactic acidosis with **Sitagliptin Combo Sandoz** if you:

- have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye
- have liver problems
- drink alcohol very often, or drink a lot of alcohol in a short time
- are dehydrated (lost a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids
- have surgery
- have a heart attack, severe infection, or stroke
- are 65 or older

The best way to avoid having a problem with lactic acidosis from metformin is to tell your doctor if you have any of the problems in the list above. Your doctor may decide to stop your **Sitagliptin Combo Sandoz** for a while if you have any of these things.

Pancreatitis (inflammation of the pancreas) which may be severe and lead to death.

Certain medical problems increase your risk of getting pancreatitis. Stop taking **Sitagliptin Combo Sandoz** and contact your doctor right away if you have pain in your stomach area that is severe and will not go away. You may feel the pain going from your abdomen through to your back. The pain may appear with or without vomiting. These may be symptoms of pancreatitis.

Heart failure. Heart failure means your heart does not pump blood well enough.

Before you start taking Sitagliptin Combo Sandoz, tell your doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor right away if you have any of the following symptoms:

- increasing shortness of breath or trouble breathing, especially when you lie down
- swelling or fluid retention, especially in the feet, ankles or legs
- an unusually fast increase in weight
- unusual tiredness

These may be symptoms of heart failure.

Kidney problems (frequency not known), sometimes requiring dialysis.

Low vitamin B₁₂ (vitamin B₁₂ deficiency). Using metformin for long periods of time may cause a decrease in the amount of vitamin B₁₂ in your blood, especially if you have had low vitamin B₁₂ blood levels before.

Low blood sugar (hypoglycemia). Common (may affect up to 1 in 10 people). If you take **Sitagliptin Combo Sandoz** with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take **Sitagliptin Combo Sandoz**.

Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery.

Serious allergic reactions (frequency not known) can happen with **Sitagliptin Combo Sandoz** or sitagliptin, one of the medicines in **Sitagliptin Combo Sandoz**. Symptoms of a serious allergic reaction to **Sitagliptin Combo Sandoz** may include rash, raised red patches on your skin (hives), or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking **Sitagliptin Combo Sandoz** and talk to your doctor right away or go get emergency medical assistance. Your doctor may prescribe you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

Joint pain (frequency not known). Some people who take medicines called DPP-4 inhibitors, one of the medicines in **Sitagliptin Combo Sandoz**, may develop joint pain that can be severe. Contact your doctor if you have severe joint pain.

Skin reactions (frequency not known). Some people who take medicines called DPP-4 inhibitors, one of the medicines in **Sitagliptin Combo Sandoz**, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your doctor right away if you develop blisters or an injury of the outer layer of your skin (erosion). Your doctor may tell you to stop taking **Sitagliptin Combo Sandoz**.

The most common side effects (may affect more than 1 in 10 users) of

Sitagliptin Combo Sandoz include:

- stuffy or runny nose and sore throat
- upper respiratory infection
- diarrhea
- nausea and vomiting
- gas, upset stomach, indigestion
- weakness
- headache

- low blood sugar (hypoglycemia) when used in combination with certain medicines, such as a sulfonylurea or insulin

Taking **Sitagliptin Combo Sandoz** with meals can help lessen the common stomach side effects of metformin that usually happen at the beginning of treatment. If you have unusual or sudden stomach problems, talk with your doctor. Stomach problems that start later during treatment may be a sign of something more serious.

Sitagliptin Combo Sandoz may have other side effects, including:

- **Swelling of the hands or legs.** Swelling of the hands and legs can happen if you take **Sitagliptin Combo Sandoz** in combination with rosiglitazone. Rosiglitazone is another type of diabetes medicine

- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

These are not all of the possible side effects of **Sitagliptin Combo Sandoz**. For more information, ask your doctor.

Tell your doctor if you have any side effect that bothers you, or does not go away.

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use **Sitagliptin Combo Sandoz** after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of the indicated month.

Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

Storage conditions: Do not store above 25°C.

6. Additional information

In addition to the active ingredients, this medicine also contains:

cellulose microcrystalline, povidone K30, croscarmellose sodium, sodium stearyl fumarate, sodium laurilsulfate

The coating contains:

hypromellose, titanium dioxide (E171), triethyl citrate, hydroxypropyl cellulose, talc, red iron oxide (E172), yellow iron oxide (E172)

What the medicine looks like and contents of the pack:

Sitagliptin Combo Sandoz 50/850 mg tablets are light orange, film-coated, biconvex, oval tablets, debossed with 'SM 2' on one side.

Sitagliptin Combo Sandoz 50/1000 mg tablets are light red, film-coated, biconvex, oval tablets, debossed with 'SM 3' on one side.

Pack sizes: 56, 60 tablets in blisters.

Not all pack sizes may be marketed.

Registration holder and importer's name and address:

Sandoz Pharmaceuticals Israel Ltd., P.O.Box 9015, Tel Aviv, Israel

Revised in May 2025.

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:

Sitagliptin Combo Sandoz 50/850 mg: 177-35-36763-99

Sitagliptin Combo Sandoz 50/1000 mg: 177-36-36764-99