

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Sitar 25

Film-coated tablets

Each film-coated tablet contains:
Sitagliptin (as hydrochloride) 25 mg

Sitar 50

Film-coated tablets

Each film-coated tablet contains:
Sitagliptin (as hydrochloride) 50 mg

Sitar 100

Film-coated tablets

Each film-coated tablet contains:
Sitagliptin (as hydrochloride) 100 mg

For a list of inactive ingredients and allergens in the preparation, see section 6 "Further information". See also section 2.8 "Important information about some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine.

- This leaflet contains concise information about the medicine. If you have further questions, refer to the 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 to you that their medical condition is similar.
- This medicine is not intended for administration to children and adolescents under 18 years of age.

1. WHAT IS SITAR INTENDED FOR?

Sitar is indicated as an adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus.

Important limitations of use:

Sitar should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, and will not be effective in these situations.

Sitar has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at high risk for the development of pancreatitis while using Sitar.

Therapeutic group: DPP-4 enzyme inhibitors.

Sitar belongs to a group of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), which are taken orally, and lower blood sugar levels in adult patients with type 2 diabetes mellitus.

2. BEFORE USING SITAR

2.1 Do not use Sitar if:

- you are sensitive (allergic) to any of the ingredients of Sitar (see section 6 "Further information" for a complete list of ingredients in Sitar). Symptoms of a serious allergic reaction to Sitar 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.

2.2 Special warnings regarding use of Sitar

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

- you suffer or have suffered in the past from pancreatitis (inflammation of the pancreas), gallstones, alcoholism or very high blood triglyceride levels. These medical conditions may increase your chance of getting pancreatitis (see section 4 "Side effects")
- you have kidney problems
- you are pregnant or plan to become pregnant (see section 2.6 "Pregnancy and breastfeeding")
- you are breastfeeding or plan to breastfeed (see section 2.6 "Pregnancy and breastfeeding")
- you suffer from heart failure. Heart failure means your heart does not pump blood well enough
Before you start taking Sitar, 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
 - a remarkably rapid increase in weight
 - unusual fatigueThese may be symptoms of heart failure

2.3 Tests and follow-up

Your doctor will refer you for blood tests to check your kidney function before and during treatment with Sitar. Check your blood sugar as your doctor has explained to you.

Your doctor will monitor your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

2.4 Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

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.

2.5 Using Sitar with food

Sitar can be taken with or without food.

2.6 Pregnancy and breastfeeding

It is not known whether Sitar will harm your fetus. If you are pregnant, or planning a pregnancy, talk with your doctor about the best way to control your blood sugar during pregnancy. It is not recommended to take Sitar during pregnancy.

It is not known whether Sitar will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking Sitar.

2.7 Driving and using machines

The medicine has no known influence on the ability to drive and use machines. However, dizziness and drowsiness could occur, which may affect your ability to drive or use machines.

Taking Sitar in combination with medicines called sulfonylurea or with insulin may cause hypoglycemia, which may affect your ability to drive and use machines.

2.8 Important information about some of the ingredients of the medicine

Sitar contains sodium. This medicinal preparation contains less than 1 mmol sodium (23 mg) per tablet and is essentially 'sodium-free'.

3. HOW SHOULD YOU USE SITAR?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual recommended dose is one tablet, once a day.

Do not exceed the recommended dose.

Sitar can be taken with or without food. Swallow the medicine with a small amount of water. No information is available regarding crushing/halving/chewing of the tablets.

Your doctor may tell you to take Sitar along with other diabetes medicines. Low blood sugar levels may happen more often when Sitar is taken with certain other diabetes medicines (see section 4 "Side effects").

This medicine is not intended for administration to children and adolescents under 18 years of age.

When your body is under various 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 Sitar.

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.

If you have accidentally taken a higher dosage of Sitar

If you take too much Sitar, call your doctor right away. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take Sitar

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 two doses of Sitar at the same time.

Continue to take the medicine as recommended by the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Sitar may cause side effects in some users.

Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

Sitar may cause serious side effects, including:

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

Certain medical problems make you more likely to get pancreatitis.

Before you start treatment with Sitar, tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, high blood triglyceride levels. Stop taking Sitar and refer to your doctor right away if you have pain in your abdominal area that is severe and will not go away. You may feel the pain radiating from your abdomen to your back. The pain can occur with or without vomiting. These may be symptoms of pancreatitis.

2. Heart failure.

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

Before you start taking Sitar, 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 especially rapid increase in weight, unusual tiredness. These may be symptoms of heart failure.

3. Kidney problems (unknown frequency), sometimes requiring dialysis.

4. Low blood sugar (hypoglycemia). Common (may affect up to 1 in 10 users). If you take Sitar with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of suffering from low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you use Sitar. Signs and symptoms of low blood sugar may include: headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery.

5. Serious allergic reactions (unknown frequency). Allergic reactions, which may be serious, including rash, hives (raised red patches on the skin) and 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 Sitar and call your doctor right away or get emergency medical help. Your doctor may prescribe a medicine for you for your allergic reaction and prescribe a different medicine to treat your diabetes.

6. Joint pain (unknown frequency). Some users who take medicines called DPP-4 inhibitors like Sitar may develop joint pain that can be severe. Call your doctor if you have severe joint pain.

7. Skin reactions (unknown frequency). Some people who take medicines called DPP-4 inhibitors, one of the medicines in Sitar, may develop a skin reaction called bullous pemphigoid that may require treatment in a hospital. Tell your doctor right away if you develop blisters or damage of the outer layer of your skin (erosion). Your doctor may tell you to stop taking Sitar.

The most common side effects of Sitar include:

- Upper respiratory infection
- Stuffy or runny nose and sore throat and headache
- Sitar may have additional side effects, including:
 - Stomach discomfort and diarrhea
 - Swelling of the hands or legs, when Sitar is used with metformin and rosiglitazone. Rosiglitazone is another type of diabetes medicine
- Constipation
- Joint pains
- Muscle pains
- Arm or leg pain
- Back pains
- Vomiting
- Interstitial lung disease
- Osteoarthritis
- Dizziness
- Itching
- Blisters

These are not all the possible side effects of Sitar. For more information, ask your doctor or pharmacist.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<http://sideeffects.health.gov.il>

Additionally, you can report to "Unipharm Ltd."

5. HOW TO STORE SITAR?

- Avoid poisoning! This medicine, and any other medicine, should be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- There are no special storage conditions. It is advisable to store at room temperature.
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

6.1 What does Sitar contain?

In addition to the active ingredient, the medicine also contains:

Calcium Hydrogen Phosphate, Cellulose Microcrystalline, Croscarmellose Sodium, Sodium Stearyl Fumarate, and Magnesium Stearate.

The tablet film-coating contains the following inactive ingredients:

Sitar 25:

Lactose Monohydrate, Hypromellose, Titanium Dioxide, Triacetin and Iron Oxide Red.

Sitar 50:

Polyvinyl alcohol, Titanium Dioxide, Macrogol/Polyethylene glycol, Talc, Iron Oxide Yellow and Iron Oxide Red.

Sitar 100:

Polyvinyl alcohol, Titanium Dioxide, Macrogol/Polyethylene glycol, Talc, Iron Oxide Yellow and Iron Oxide Red.

6.2 What Sitar looks like and contents of the package

Sitar film-coated tablets are available in three strengths:

Sitar 25 are pink, round, biconvex, film-coated tablets, debossed with "LC" on one side and plain on the other.

Sitar 50 are orange, round, biconvex, film-coated tablets, debossed with "C" on one side and plain on the other.

Sitar 100 are beige, round, biconvex, film-coated tablets, debossed with "L" on one side and plain on the other.

Package sizes:

Sitar 25: package sizes of 14, 28, 30 film-coated tablets.

Sitar 50: package sizes of 14, 28, 30 film-coated tablets.

Sitar 100: package sizes of 14, 28, 30 film-coated tablets.

Not all package sizes may be marketed.

Name of Registration holder and Importer:

Unipharm Trading Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Revised in April 2023 according to MOH guidelines.

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

Sitar 25: 172.96.36636.99

Sitar 50: 172.97.36637.99

Sitar 100: 172.98.36638.99