

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Sitar Plus 50 / 500

Film-coated tablets

Each tablet contains:
Sitagliptin (as hydrochloride) 50 mg
Metformin hydrochloride 500 mg

Sitar Plus 50 / 850

Film-coated tablets

Each tablet contains:
Sitagliptin (as hydrochloride) 50 mg
Metformin hydrochloride 850 mg

Sitar Plus 50 / 1000

Film-coated tablets

Each tablet contains:
Sitagliptin (as hydrochloride) 50 mg
Metformin hydrochloride 1000 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6 "Further Information". Also see section 2.7 "Important information about some of the ingredients of the medicine".

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

- This leaflet contains concise information about **Sitar Plus**. If you have further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed to treat 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 under 18 years of age.

1. WHAT IS SITAR PLUS INTENDED FOR?

1.1 What is Sitar Plus?

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

1.2 What is Sitar Plus used for?

Sitar Plus is a tablet that contains 2 prescription medicines, sitagliptin and metformin, which lower blood sugar. Sitagliptin, which belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), and metformin, which belongs to the biguanide class of medicines, work together to control blood sugar levels in patients with type 2 diabetes mellitus, for whom this combination is appropriate.

Sitar Plus, along with a recommended diet and exercise program, is intended to lower blood sugar levels in patients with type 2 diabetes.

2. BEFORE USING SITAR PLUS

2.1 Do not use Sitar Plus if:

- You have type 1 diabetes mellitus.
- You have severely impaired renal function (your doctor will determine your level of renal function impairment).
- You have diabetic ketoacidosis (increased ketone levels in your blood or urine: diabetes complication which includes high blood sugar levels, rapid weight loss, nausea or vomiting).
- You are allergic to any of the ingredients in **Sitar Plus** (see section 6 "Further information" for a complete list of the ingredients in **Sitar Plus**). Symptoms of a severe allergic reaction to **Sitar Plus** 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 Plus

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

- You have or have had inflammation of the 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 **Sitar Plus** (see section 4 "Side effects").
- You have kidney problems.
- You have liver problems.
- You have or have had stones in the gallbladder.
- You have high blood triglyceride levels.
- You have heart failure.
- You drink alcohol very often, or drink a lot of alcohol within short periods of time. If 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 have to stop taking **Sitar Plus** for a short period of time. Consult your doctor about when you should stop taking **Sitar Plus** and when you should start taking **Sitar Plus** 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 section 2.6 "Pregnancy, breastfeeding and fertility").
- You are breastfeeding or plan to breastfeed (see section 2.6 "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 section 2.6 "Pregnancy, breastfeeding and fertility").

Stop taking **Sitar Plus** and contact your doctor immediately if you have severe pain in your stomach area that does not go away. You may feel the pain going from your stomach to your back. The pain may occur with or without vomiting. These may be symptoms of pancreatitis.

2.3 Tests and follow-up

Check your blood sugar as instructed by the doctor. Your doctor will monitor your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C. Your doctor may do blood tests to check your vitamin B₁₂ levels.

2.4 Drug interactions

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

- Especially if you are taking:
- Topiramate (for the treatment of convulsions and migraines).
 - Acetazolamide (for the treatment of edema, glaucoma and seasickness).
 - Dolutegravir (for the treatment of HIV infection).
 - Cimetidine (for the treatment of ulcers).
 - Ranolazine.
 - Vandetanib.

Sitar Plus may affect the way other medicines work and other medicines may affect the way **Sitar Plus** 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.

2.5 Use of Sitar Plus and food

Take **Sitar Plus** with meals to help to lower your chance of suffering from digestive system disturbances.

2.6 Pregnancy, breastfeeding and fertility

- If you are pregnant or plan to become pregnant: it is not known if **Sitar Plus** 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 **Sitar Plus** will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking **Sitar Plus**.
- If you are a woman who has not gone through menopause (premenopausal) who does not have periods regularly or at all: **Sitar Plus** 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 immediately if you become pregnant while taking **Sitar Plus**.

2.7 Important information about some of the ingredients of the medicine

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

Sitar Plus contains lactose. If you have been told by the doctor that you have an intolerance to certain types of sugar, please refer to your doctor before taking **Sitar Plus**.

3. HOW SHOULD YOU USE SITAR PLUS?

Always use **Sitar Plus** according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

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

Your doctor will tell you how many **Sitar Plus** tablets to take and when you should take them.

Do not exceed the recommended dose.

Your doctor may change your **Sitar Plus** dosage, if needed. Take **Sitar Plus** with meals to help reduce the chance of you suffering from digestive system disturbances.

Your doctor may tell you to take **Sitar Plus** together with certain other diabetes medicines. Low blood sugar (hypoglycemia) may happen more often when **Sitar Plus** is taken with certain other diabetes medicines (see section 4 "Side effects"). This medicine is not intended for administration to children under 18 years of age.

There is no information about crushing, halving, or chewing these tablets. Tell your doctor if you cannot swallow **Sitar Plus** tablets whole. If you have reduced kidney function, the doctor may prescribe you a lower dosage.

- If you take too much **Sitar Plus**, talk to your doctor immediately.
- 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 miss taking a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the forgotten dose and go back to your regular dosing schedule. Do not take 2 doses of **Sitar Plus** at the same time.

You may need to stop taking **Sitar Plus** for a short period of time. Contact your doctor for instructions if you:

- Are dehydrated (have lost too much body fluids). Dehydration can occur if you are sick with severe vomiting, diarrhea or fever, or if you drink a lot less fluid than normal.
- Plan to have surgery.
- Are going to get an injection of dye or contrast agent for an x-ray (see section 2.2 "Special warnings regarding use of **Sitar Plus**" 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 immediately if you have any of these conditions and follow your doctor's instructions.

Stay on your prescribed diet and exercise program while taking **Sitar Plus**.

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 **Sitar Plus** as long as your doctor tells you to do so.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting your doctor.

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

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

4. SIDE EFFECTS

As with any medicine, use of **Sitar Plus** 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 Plus may cause serious side effects, including:

4.1 Lactic Acidosis. Metformin, one of the medicines in Sitar Plus, may cause a rare (can occur in up to 1 in 10,000 users), but serious condition called lactic acidosis (a buildup of an acid in the blood) that may cause death. Lactic acidosis is a medical emergency that must be treated in a hospital. Stop taking **Sitar Plus** and talk to your doctor immediately if you have any of the following symptoms, which may 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 (abnormal) 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 suffer from other conditions that, in combination with the metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, since you have a higher chance of developing lactic acidosis with **Sitar Plus** 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 period of time.
- Are dehydrated (lost a large amount of body fluids). This may happen if you are sick with a fever, vomiting or diarrhea. Dehydration can also happen when you sweat a lot during activity or exercise and do not drink enough fluids.
- Are undergoing surgery.
- Have a heart attack, severe infection, or stroke.
- Are 65 years of age or older.

The best way to avoid having 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 **Sitar Plus** for a while if you have any of these conditions.

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

Certain medical problems increase your chance of getting pancreatitis.

Stop taking **Sitar Plus** and contact your doctor immediately if you have severe pain in the stomach area that does not go away. You may feel the pain going from your stomach to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

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

Before you start taking Sitar Plus, tell your doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor immediately 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 fast increase in weight.
- Unusual tiredness.

These may be symptoms of heart failure.

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

4.5 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 in the past.

4.6 Low blood sugar (hypoglycemia). Common (may occur in up to 1 in 10 people). If you take **Sitar Plus** with another medicine that may 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 take **Sitar Plus**.

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

4.7 Serious allergic reactions (frequency not known) can occur with **Sitar Plus** or sitagliptin, one of the medicines included in **Sitar Plus**. Symptoms of a severe allergic reaction to **Sitar Plus** 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 severe allergic reaction, stop taking **Sitar Plus** and talk to your doctor immediately or get emergency medical help. Your doctor may prescribe you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

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

4.9 Skin reactions (frequency not known). Some people who take medicines called DPP-4 inhibitors, one of the medicines in **Sitar Plus**, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your doctor immediately if you develop blisters or breakdown of the outer layer of your skin (erosion). Your doctor may tell you to stop taking **Sitar Plus**. The most common side effects (can occur in more than 1 in 10 people) of **Sitar Plus** include:

- Stuffy or runny nose and sore throat.
- Upper respiratory tract 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 **Sitar Plus** 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.

Sitar Plus may have other side effects, including:

- Swelling of the hands or legs. Swelling of the hands or legs may occur if you take **Sitar Plus** in combination with rosiglitazone. Rosiglitazone is another type of diabetes medicine.
- Joint pains.
- Muscle aches.
- Arm or leg pain.
- Back pain.
- Itching.
- Blisters.

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

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

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 with 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. Additionally, you can report to "Unipharm Ltd." at: <https://unipharm.co.il/>

5. HOW SHOULD SITAR PLUS BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept 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 **Sitar Plus** after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

6.1 What does Sitar Plus contain?

In addition to the active ingredients, the medicine also contains: Cellulose Microcrystalline, Povidone (K29/32), Sodium Stearyl Fumarate, Sodium Laurilsulfate, Purified Water.

The tablet film coating (50 / 500) contains the following inactive ingredients:

Polyvinyl alcohol, Titanium Dioxide (E171), Macrogl/Polyethylene glycol, Talc, Iron Oxide yellow, Iron Oxide Red.

The tablet film coating (50 / 850) contains the following inactive ingredients:

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

The tablet film coating (50 / 1000) contains the following inactive ingredients:

Polyvinyl alcohol, Macrogl/Polyethylene glycol, Talc, Titanium Dioxide, Iron Oxide Red, Iron Oxide Black.

6.2 What Sitar Plus looks like and contents of the package

Sitar Plus film-coated tablets are available in three strengths: **Sitar Plus 50 / 500** are film-coated, oval shaped, biconvex orange tablets, debossed "S475" on one side and blank on the other.

Sitar Plus 50 / 850 are film-coated, oval shaped, biconvex pink tablets, debossed "S476" on one side and blank on the other.

Sitar Plus 50 / 1000 are film-coated, oval shaped, biconvex, brown tablets, debossed "S477" on one side and blank on the other.

Package sizes:

Sitar Plus 50 / 500: package sizes of 28, 56, 198 film-coated tablets.

Sitar Plus 50 / 850: package sizes of 14, 28, 30, 56, 60 film-coated tablets.

Sitar Plus 50 / 1000: package sizes of 14, 28, 30, 56, 60 film-coated tablets.

Not all package sizes may be marketed.

Registration holder and importer: Unipharm Trading Ltd., P.O. Box 21429, Tel Aviv, 6121301.


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

Sitar Plus 50 / 500: _____, 36970.

Sitar Plus 50 / 850: 168.97.36684.99

Sitar Plus 50 / 1000: 168.98.36685.99

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