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

This medicine is dispensed with a doctor's prescription only

Sitin 25 mg

Film-coated tablets

Sitin 50 mg

Film-coated tablets

Sitin 100 mg

Film-coated tablets

Active ingredient

Each film-coated tablet contains:

sitagliptin (as hydrochloride monohydrate) 25 mg

sitagliptin (as hydrochloride monohydrate) 50 mg

sitagliptin (as hydrochloride monohydrate) 100 mg

For a list of inactive ingredients in this medicine, see Section 6 'FURTHER INFORMATION'. See also section 2 'Important information about some of the ingredients in this medicine'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about **Sitin**. 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 to you that their ailment is similar.

1. WHAT IS SITIN INTENDED FOR?

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

Important limitations of use:

Sitin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

Sitin has not been studied in patients with a history of pancreatitis (inflammation of the pancreas). It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using **Sitin**.

Therapeutic group: DPP-4 enzyme inhibitors.

Sitin is a member of a class of medicines taken by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

2. BEFORE USING SITIN

Do not use Sitin if:

you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6 'FURTHER INFORMATION').

Symptoms of a serious allergic reaction to **Sitin** 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.

Special warnings regarding use of Sitin

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

- you have or have had pancreatitis (inflammation of the pancreas), gallstones, alcoholism or very high blood triglyceride levels. These medical conditions can 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 'Pregnancy and breastfeeding').

- you are breastfeeding or plan to breastfeed (see section 2 'Pregnancy and breastfeeding').
- you have **heart failure**. Heart failure means your heart does not pump blood well enough.
Before you start taking Sitin, 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 tirednessThese may be symptoms of heart failure.

Children and adolescents

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

Tests and follow-up

Your doctor will send you for blood tests to check your kidney function before and during your treatment with **Sitin**.

Check your blood sugar as your doctor tells you to.

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

Interactions with other medicines

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

Using this medicine and food

Take **Sitin** with food.

Pregnancy and breastfeeding

It is not known if **Sitin** will harm your unborn baby. If you are pregnant, or plan to become pregnant, talk with your doctor about the best way to control your blood sugar during pregnancy. It is not recommended to take **Sitin** during pregnancy.

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

Driving and using machines

This 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 **Sitin** in combination with medicines called sulfonylurea or with insulin, can cause hypoglycemia, which may affect your ability to drive and use machines.

Important information about some of the ingredients of the medicine

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

3. HOW SHOULD YOU USE SITIN?

Always use this medicine according to your doctor's instructions. You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.

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

The recommended dose is usually 1 tablet, once a day.

Do not exceed the recommended dose.

Take **Sitin** with food.

Swallow the medicine with a small amount of water.

No information is available regarding crushing/splitting/chewing of the tablets.

Your doctor may tell you to take **Sitin** along with other diabetes medicines. Low blood sugar can happen more often when **Sitin** is taken with certain other diabetes medicines (see section 4 'SIDE EFFECTS').

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

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 **Sitin**.

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

If you have accidentally taken a higher dose of Sitin

If you take too much **Sitin**, 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 medicine with you.

If you forget to take Sitin

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 two doses of **Sitin** at the same time.

Continue to take this 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 your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this product, consult with a doctor or a pharmacist.

4. SIDE EFFECTS

As with any medicine, **Sitin** may cause side effects in some users.

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

Sitin can cause serious side effects, including:

- **Pancreatitis (inflammation of the pancreas) which may be severe and lead to death.**
Certain medical problems may increase your risk of getting pancreatitis.
Before you start taking Sitin, tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, high blood triglyceride levels.
Stop taking **Sitin** and call your doctor right away if you have pain in your stomach area that is severe and does not go away. The pain may be felt 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 Sitin, 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 blood sugar (hypoglycemia).** Common (may appear in up to 1 in 10 users). If you take **Sitin** 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 use **Sitin**. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heart beat, sweating, feeling jittery.
- **Severe allergic reactions.** (frequency not known). Allergic reactions, which may be severe, including rash, hives (raised red patches on your 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 severe allergic reaction, stop taking **Sitin** and contact your doctor right away or go get emergency medical help. 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 like **Sitin**, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.
- **Skin reactions** (frequency not known). Some people who take medicines called DPP-4 inhibitors like **Sitin** 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 injury of the outer layer of your skin (erosion). Your doctor may tell you to stop taking **Sitin**.

The most common side effects of **Sitin** include:

- Upper respiratory infection
- Stuffy or runny nose, sore throat and headache.

Sitin may have additional side effects, including:

- Stomach upset and diarrhea
- Swelling of the hands or legs, when **Sitin** is used with metformin and rosiglitazone. Rosiglitazone is another type of diabetes medicine
- Constipation
- Joint pain
- Muscle pain
- Arm or leg pain
- Back pain
- Vomiting
- Interstitial lung disease
- Osteoarthritis
- Dizziness
- Itching
- Blisters

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

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, must 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 a doctor.
- Do not take **Sitin** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of that month.
- Store below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

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

Calcium hydrogen phosphate, microcrystalline cellulose, crospovidone, sodium stearyl fumarate, magnesium stearate vegetable.

The tablet film coating contains the following inactive ingredients:

Polyvinyl alcohol, titanium dioxide, macrogol, talc, yellow iron oxide and iron oxide red.

What Sitin looks like and contents of the pack:

Sitin film-coated tablets are available in three strengths:

Sitin 25 mg are pink, round, film-coated tablets, debossed "25" on one side and plain on the other.

Sitin 50 mg are light beige, round film-coated tablets, debossed "50" on one side and plain on the other.

Sitin 100 mg are beige, round, film-coated tablets, debossed "100" on one side and plain on the other.

Pack size:

14, 28, 30, 56, 90 or 98 film-coated tablets.

Not all pack sizes may be marketed.

Registration holder's name and address:

Halperin N.H Medic Ltd., 19 Zur St., Ma'ayan Zvi 30805

Manufacturer's name and address:

Pharmazac S.A., 31 Naousis Str., 104 47 Athens, Greece

Revised in July 2025.

Drug registration no. listed in the official registry of the Ministry of Health:

Sitin 25 mg: 178-89-37562-99

Sitin 50 mg: 178-90-37563-99

Sitin 100 mg: 178-91-37564-99