

Patient package insert according to Pharmacist's Regulations (Preparations)- 1986

This medicine can be sold by physician's prescription only

Sitagliptin Vitamed 25 mg

Film-coated tablets

Sitagliptin Vitamed 50 mg

Film-coated tablets

Sitagliptin Vitamed 100 mg

Film-coated tablets

Each film-coated tablet contains:

Sitagliptin (as Hydrochloride Monohydrate) 25 mg

Sitagliptin (as Hydrochloride Monohydrate) 50 mg

Sitagliptin (as Hydrochloride Monohydrate) 100 mg

For the list of inactive ingredients, see section 6 "Additional information". Also see section 2.8 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask 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 use in children and adolescents under 18 years of age.

1. What is this medicine intended for?

Sitagliptin Vitamed is intended to improve blood sugar control in adults with type 2 diabetes, in combination with diet and physical activity.

Important usage restrictions:

Do not use **Sitagliptin Vitamed** in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it will not be effective in these conditions.

Sitagliptin Vitamed has not been tested in patients with a history of pancreatitis. It is not known whether patients with a history of pancreatitis are at increased risk of developing pancreatitis during the use of **Sitagliptin Vitamed**.

Therapeutic group: DPP-4 enzyme inhibitors.

Sitagliptin Vitamed belongs to a group of oral medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), which lower blood sugar levels in adults with type 2 diabetes.

2. Before using this medicine

2.1 Do not use the medicine if:

- You are allergic (hypersensitive) to the active ingredient (Sitagliptin) or to any of the other ingredients this medicine contains (see section 6 "Additional information").
Symptoms of a serious allergic reaction to **Sitagliptin Vitamed** may include: Rash, raised red spots on your skin (hives), or swelling of the face, lips, tongue and throat, which may cause difficulty breathing or swallowing.

2.2 Special warnings regarding the use of the medicine

Before starting treatment with Sitagliptin Vitamed, tell your doctor about all your medical conditions, including if:

- You have or have had pancreatitis, gallstones, alcoholism, or very high blood triglyceride levels.
- These medical conditions may increase your risk of developing pancreatitis (see section 4 "Side Effects").
- You have kidney problems.
- You are pregnant or planning to become pregnant (see section 2.6 "Pregnancy and breastfeeding").
- You are breastfeeding or planning to breastfeed (see section 2.6 "Pregnancy and breastfeeding").
- You have heart failure. Heart failure means your heart does not pump blood well enough.

Before you start taking Sitagliptin Vitamed, tell your doctor if you have ever had heart failure or have kidney problems. Contact your doctor immediately if you experience any of the following symptoms:

- Increasing shortness of breath or difficulty breathing, especially when lying down
- Swelling or fluid retention, especially in the feet, ankles, or legs
- Particularly rapid weight gain
- Unusual tiredness

These may be symptoms of heart failure.

2.3 Tests and onitoring

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

Check your blood sugar as instructed by your doctor.
Your doctor will monitor your diabetes through regular blood tests, including blood sugar and HbA1C levels.

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 are taking. Keep a list of your medicines and show it to your doctor and pharmacist when you receive a new medicine.

2.5 Use of this medicine and food

Sitagliptin Vitamed may be taken with or without food.

2.6 Pregnancy and breastfeeding

It is not known whether **Sitagliptin Vitamed** will harm your unborn baby. If you are pregnant or to become pregnant, talk to your doctor about the best way to control your blood sugar during pregnancy. **Sitagliptin Vitamed** is not recommended during pregnancy.

It is not known whether **Sitagliptin Vitamed** passes into your breast milk. Talk to your doctor about the best way to feed your baby if you are taking **Sitagliptin Vitamed**.

2.7 Driving and use of machines

The effect of this medicine on the ability to drive and use machines is unknown. However, dizziness and drowsiness may occur and affect your ability to drive or operate machines.

Taking **Sitagliptin Vitamed** together with medicines called sulfonylureas or with insulin may cause low blood sugar (hypoglycemia), which may affect the ability to drive and use machines.

2.8 Important information about some of the ingredients of the medicine

Sitagliptin Vitamed contains sodium. This medicine contains less than 1 millimole of sodium (23 mg) per tablet, that is to say, essentially "sodium-free".

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

The usual dose is generally one tablet once a day.

Do not exceed the recommended dose.

Sitagliptin Vitamed can be taken with or without food.

Swallow the medicine with a small amount of water.

There is no information regarding crushing, splitting, or chewing the tablets.

Your doctor may instruct you to take **Sitagliptin Vitamed** together with other diabetes medicines. Low blood sugar levels may occur more frequently when **Sitagliptin Vitamed** is taken together with certain other diabetes medicines (see section 4 "Side Effects").

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When your body is under various types of stress such as fever, trauma (e.g., car accident), infection, or surgery, the amount of diabetes medicine you need may change. Inform your doctor immediately if you any of these conditions occur and follow your doctor's instructions.

Continue following the diet prescribed to you and your physical activity program while taking **Sitagliptin Vitamed**.

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

If you have accidentally taken a higher dosage of Sitagliptin Vitamed

If you take too much **Sitagliptin Vitamed**, contact your doctor immediately.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take Sitagliptin Vitamed

If you miss a dose, take it as soon as you remember. If you do not remember until it is time to take the next dose, skip the missed dose and return to your regular dosing schedule. Do not take two doses of **Sitagliptin Vitamed** at the same time. Continue taking the medicine as recommended by your doctor.

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 the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

As with any medicine, the use of **Sitagliptin Vitamed** 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.

Sitagliptin Vitamed may cause serious side effects, including:

- 1. Pancreatitis (inflammation of the pancreas), which may be severe and lead to death.**
Certain medical conditions increase your risk of developing pancreatitis.
Before starting treatment with Sitagliptin Vitamed, tell your doctor if you have ever had pancreatitis, gallstones, a history of alcohol abuse, or high levels of triglycerides in your blood.
Stop taking **Sitagliptin Vitamed** and contact your doctor immediately if you have severe and persistent abdominal pain. You may feel the pain radiating from your abdomen to your back. The pain may occur with or without vomiting. These may be symptoms of pancreatitis.
- 2. Heart failure.** Heart failure means that your heart does not pump blood well enough.
Before starting **Sitagliptin Vitamed**, tell your doctor if you have ever had heart failure or have kidney problems.
Contact your doctor immediately if you experience any of the following symptoms: Increasing shortness of breath or difficulty breathing, especially when lying down, swelling or fluid retention, mainly in the feet, ankles, or legs, rapid and excessive weight gain, unusual tiredness.
These may be symptoms of heart failure.
- 3. Kidney problems** (frequency not known), which may sometimes require dialysis.
- 4. Low blood sugar (hypoglycemia).** Common (may affect up to 1 in 10 people).
If you take **Sitagliptin Vitamed** with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of developing low blood sugar is higher. It may be necessary to reduce the dose of your sulfonylurea or insulin while you are using **Sitagliptin Vitamed**.
Signs and symptoms of low blood sugar may include: Headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, rapid heartbeat, sweating, and feeling nervous.
- 5. Serious allergic reactions** (frequency not known).
Allergic reactions, which may be serious, can include rash, hives (raised red patches on the skin), and swelling of the face, lips, tongue, and throat, which may cause difficulty breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking **Sitagliptin Vitamed** and contact your doctor immediately or seek urgent medical help. Your doctor may prescribe a medicine to treat your allergic reaction and prescribe a different medicine to treat your diabetes.
- 6. Joint pain** (frequency not known).
Some people taking medicines called DPP-4 inhibitors, such as **Sitagliptin Vitamed**, may develop joint pain, which can be severe. Contact your doctor if you suffer from severe joint pain.
- 7. Skin reactions** (frequency not known).
Some people taking medicines called DPP-4 inhibitors, such as **Sitagliptin Vitamed**, may develop a skin reaction called bullous pemphigoid, which may 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 advise you to stop taking **Sitagliptin Vitamed**.

The most common side effects of **Sitagliptin Vitamed** include:

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

Sitagliptin Vitamed may have additional side effects, including:

- Abdominal discomfort and diarrhea
- Swelling of the hands or legs when **Sitagliptin Vitamed** is taken with Metformin and Rosiglitazone. Rosiglitazone is another type of diabetes medicine
- Constipation
- Joint pain
- Muscle pain
- Pain in the arm or leg
- Back pain
- Vomiting

- Interstitial lung disease
- Osteoarthritis
- Dizziness
- Itching
- Blisters

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

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

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects problems associated with medications and drugs" on the Ministry of Health homepage (www.health.gov.il), which links to an online form for reporting side effects, or by following 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 closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Calcium hydrogen phosphate, Microcrystalline cellulose, Croscarmellose sodium, Sodium stearyl fumarate, Silica colloidal anhydrous, Magnesium stearate.

The tablet coating contains the following inactive ingredients:

Sitagliptin Vitamed 25 mg: Titanium dioxide, Polyvinyl alcohol, Macrogol 3350, Talc, Iron oxide yellow, Iron oxide red, Iron oxide black.

Sitagliptin Vitamed 50 mg: Polyvinyl alcohol, Titanium dioxide, Macrogol 3350, Talc, Iron oxide yellow, Iron oxide red.

Sitagliptin Vitamed 100 mg: Polyvinyl alcohol, Titanium dioxide, Macrogol 3350, Talc, Iron oxide yellow, Iron oxide red.

What the medicine looks like and what the package contains:

Sitagliptin Vitamed film-coated tablets are available in three strengths:

Sitagliptin Vitamed 25 mg: Pink, round film-coated tablets.

Sitagliptin Vitamed 50 mg: Light beige, round film-coated tablets, engraved with an "S" on one side.

Sitagliptin Vitamed 100 mg: Beige, round film-coated tablets.

Pack sizes:

Sitagliptin Vitamed 25 mg: Each pack contains 28 film-coated tablets.

Sitagliptin Vitamed 100 mg: Each pack contains 28 film-coated tablets.

Sitagliptin Vitamed 50 mg: Each pack contains 28 film-coated tablets.

Marketing authorization holder and importer:

Vitamed Pharmaceutical Industries Ltd., 6 Hatachana St., Binyamina, Israel.

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Drug registration number at the national drug registry of the Ministry of Health:

Sitagliptin Vitamed 25 mg: 178-76-37190-99

Sitagliptin Vitamed 50 mg: 178-77-37191-99

Sitagliptin Vitamed 100 mg: 178-78-37192-99