

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr SITAGLIPTIN

Sitagliptin Tablets

Read this carefully before you start taking **SITAGLIPTIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SITAGLIPTIN**.

What is SITAGLIPTIN used for?

SITAGLIPTIN is used in addition to diet and exercise to improve blood sugar levels in adult patients with type 2 diabetes mellitus:

- alone in patients who cannot take metformin
- in combination with metformin
- in combination with metformin and a sulfonylurea (e.g. glyburide, gliclazide or glimepiride)
- in combination with premixed or long/intermediate acting insulin (with or without metformin)
- in combination with pioglitazone (with or without metformin)

How does SITAGLIPTIN work?

SITAGLIPTIN contains the medicinal ingredient sitagliptin which belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). SITAGLIPTIN helps to improve the levels of insulin when blood sugar level is high, especially after a meal. SITAGLIPTIN also helps to decrease the amount of sugar made by the body. SITAGLIPTIN is unlikely to cause low blood sugar (**hypoglycemia**).

What are the ingredients in SITAGLIPTIN?

Medicinal ingredients: sitagliptin (as sitagliptin phosphate monohydrate)

Non-medicinal ingredients: black iron oxide (only the 100 mg strength), calcium hydrogen phosphate anhydrous, colloidal silicone dioxide, croscarmellose sodium, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, red iron oxide, sodium stearyl fumarate, talc, titanium dioxide and yellow iron oxide

SITAGLIPTIN comes in the following dosage forms:

Tablets: 25 mg, 50 mg, 100 mg

Do not use SITAGLIPTIN if:

- you are allergic (hypersensitive) to sitagliptin or any of the other ingredients in SITAGLIPTIN.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SITAGLIPTIN. Talk about any health conditions or problems you may have, including if you:

- have or have had pancreatitis (inflammation of the pancreas);
- have risk factors for pancreatitis such as:

- gallstones (solid particles that form in the gall bladder),
- a history of alcoholism,
- high triglyceride levels;
- have type 1 diabetes;
- have or have had diabetic ketoacidosis (increased ketones in the blood or urine);
- have or have had kidney problems;
- have liver problems;
- had an organ transplant;
- have human immunodeficiency syndrome (HIV);
- are pregnant or plan to become pregnant; SITAGLIPTIN is not recommended for use during pregnancy;
- are breastfeeding or plan to breastfeed. It is not known if SITAGLIPTIN passes into breast milk.

Other warnings you should know about:

Serious Skin Reactions and Pancreatitis:

- **SITAGLIPTIN can cause serious side effects, including:**
 - **Pancreatitis** (inflammation of the pancreas) which can be life-threatening and cause death.
 - **Serious Skin Reactions** called **Stevens-Johnson syndrome** and **bullous pemphigoid**. These reactions can happen after your first dose or up to 3 months after you start SITAGLIPTIN.

See the **Serious side effects and what to do about them** table, below for more information on these and other serious side effects.

Hypoglycemia (low blood sugar):

- When SITAGLIPTIN is used with metformin and a sulfonylurea medicine or with insulin (with or without metformin), **hypoglycemia** (low blood sugar) can occur. Lower doses of the sulfonylurea medicine or insulin may be required while you take SITAGLIPTIN. You should use caution when driving or using machines if you are taking SITAGLIPTIN with a sulfonylurea medicine or with insulin.

Blood Tests:

SITAGLIPTIN may cause abnormal blood tests. Your healthcare professional will do blood tests before you start SITAGLIPTIN and while you are taking it. They may check your blood sugar, liver function and how well your kidneys are working. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take SITAGLIPTIN

- Take SITAGLIPTIN exactly as your healthcare professional tells you to.
- SITAGLIPTIN can be taken with or without food.

Usual adult dose:

100 mg once daily. Your healthcare professionals may adjust your dose if you have kidney problems.

Overdose:

If you think you, or a person you are caring for, have taken too much SITAGLIPTIN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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 a double dose of SITAGLIPTIN to make up for a missed dose.

What are possible side effects from using SITAGLIPTIN?

These are not all the possible side effects you may have when taking SITAGLIPTIN. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Stuffy or runny nose
- Sore throat
- Vomiting
- Constipation
- Headache
- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

Serious side effects and what to do about them			
Symptoms/effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Hypoglycemia (low blood sugar – when used with metformin and a sulfonylurea, or when used with insulin with or without metformin): shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.		✓	
RARE			
Pancreatitis (inflammation of			✓

the pancreas): prolonged severe stomach pain and possible vomiting.			
Allergic reactions: rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.			✓
Serious skin reactions including Stevens-Johnson syndrome, bullous pemphigoid: blisters or breakdown of your skin.		✓	
Acute kidney failure (sometimes requiring dialysis): nausea, loss of appetite and weakness, pass little or no urine, breathlessness.			✓
VERY RARE			
Rhabdomyolysis (breakdown of damaged muscle): muscle spasms, weakness, red-brown (tea-coloured) urine.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store SITAGLIPTIN at room temperature (15°C to 30°C). Keep in well-closed containers

Keep out of reach and sight of children.

If you want more information about SITAGLIPTIN:

- Talk to your healthcare professional.

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; or the manufacturer's website www.sivem.ca, or by calling 1 855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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