

Patient Information Leaflet

SCHEDULING STATUS: S4

SITAGLIPTIN/METFORMIN 50/500 SUN PHARMA (Film coated tablets)

SITAGLIPTIN/METFORMIN 50/850 SUN PHARMA (Film coated tablets)

SITAGLIPTIN/METFORMIN 50/1000 SUN PHARMA (Film coated tablets)

(Sitagliptin/Metformin)

Sugar Free

Read all of this leaflet carefully before you are given SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA is and what it is used for
2. What you need to know before you take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA
3. How to take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA

4. Possible side effects

5. How to store SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA

6. Contents of the pack and other information

1) What SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA is and what it is used for

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA is a tablet that contains two prescription medicines, sitagliptin and metformin, which lower blood sugar levels. Sitagliptin, a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) and metformin, a member of the biguanide class of medicines, work together to control blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus or NIDDM.

Along with diet and exercise, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

Your doctor has prescribed SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA, along with diet and exercise, to help lower your blood sugar levels.

If you have any questions about how SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA works or why this medicine has been prescribed for you, ask your doctor.

2) What you need to know before you take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA

DO NOT TAKE SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA:

- If you have certain kidney problems
- If you have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties.
- If you are allergic to sitagliptin, metformin hydrochloride or any other components of SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA
- If you are going to get or receive an injection of dye or contrast agent for an x-ray procedure. Talk to your doctor about when to stop SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA and when to start again.
- If you have uncontrolled diabetes, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- If you are breast-feeding
- If you have liver problems
- If you drink alcohol to excess (either every day or only from time to time)

Warnings and precautions

Hypersensitivity Reactions: There have been post-marketing reports of serious hypersensitivity reactions in patients treated with sitagliptin, one of the components of **SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA**. These reactions include an acute life threatening hypersensitivity disorder, swelling under the skin and shedding of the skin conditions including Stevens-Johnson syndrome (rare serious disorder of the skin and mucous membrane, a reaction to medication that start with flu-like symptoms followed by a painful rash that spreads and blisters). Onset of these reactions occurred within the first 3 months after initiation of treatment with sitagliptin, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue combination of sitagliptin and metformin immediately, and institute an alternative class of medicines for treatment for diabetes.

Talk to your doctor, pharmacist or nurse before taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA:

- If you have kidney problems
- If you have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- If you have liver problems
- If you have heart problems
- If you are older than 80 years. Patients over 80 years should not take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA unless their kidney function is checked and it is normal.
- If you drink alcohol a lot (all the time or short-term “binge” drinking)

- If you have or have had an allergic reaction to sitagliptin, metformin, or SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA
- If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid.
- If you are taking a sulphonylurea or insulin, diabetes medicines, together with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin

Risk of lactic acidosis

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions. Stop taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:

- Vomiting
- Stomach ache (abdominal pain)
- Muscle cramps
- A general feeling of not being well with severe tiredness
- Difficulty in breathing
- Reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Pancreatitis (inflammation of the pancreas) can be a serious, potentially life-threatening medical condition. Stop taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

If you need to have major surgery you must stop taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA.

During treatment with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

Children and adolescents

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA has not been studied in children under 18 years of age.

Use in the elderly

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.

Other medicines and SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines). If they are taken with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA their effect or the effect of SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA may be changed.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- Medicines which increase urine production (diuretics)
- Medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- Specific medicines for the treatment of bronchial asthma (β -sympathomimetics)
- Iodinated contrast agents or alcohol-containing medicines
- Certain medicines used to treat stomach problems such as cimetidine
- Vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer)
- Digoxin (to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if taking with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA.
- Nifedipine (calcium channel blocker medication used to manage angina, high blood pressure)
- Amiloride (medications to treat high blood pressure or swelling due to heart failure or cirrhosis of the liver).

- Morphine (pain medication)
- Procainamide, quinidine (medication of the antiarrhythmic class used for the treatment of cardiac arrhythmias).
- Quinine (used to treat malaria and babesiosis)
- Ranitidine (medication that decreases stomach acid production)
- Trimethoprim or vancomycin (antibiotic used mainly in the treatment of several infections)

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA with food and drink:

Take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA with meals to lower your chance of an upset stomach.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you might get pregnant, you should use a reliable method of contraception during treatment with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA.

If you are breast-feeding, tell your doctor. You should not breast-feed during treatment with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA.

Driving and using machines:

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported with sitagliptin, which may affect your ability to drive or use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

3) How to take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Take one tablet:

- Twice daily by mouth
 - With meals to lower your chance of an upset stomach.
 - Your doctor may need to increase your dose to control your blood sugar.
- If you have reduced kidney function, your doctor may prescribe a lower dose.
- You should continue the diet recommended by your doctor during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day.

This medicine alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When this medicine is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

Your doctor will determine the appropriate dose you need to take, as well as if and when you need to stop treatment with SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA.

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

Method of administration

Take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA with meals to lower your chance of an upset stomach.

If you take more SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA than you should:

If you take more than the prescribed dosage of this medicine, contact your doctor immediately. Go to the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing.

If you forget to take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA:

Do not worry. If you remember later on that day, take that day's dose as usual. If you miss a whole day's dose take the normal dose on the next day. Do not take a double dose to make up for a forgotten tablet. If you are not sure ask your doctor or pharmacist.

If you stop taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA:

Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first. If you stop taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA, your blood sugar may rise again.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4) Possible side effects

SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA can have side effects.

Not all side effects reported for SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA, please consult your health care provider for advice

If any of the following happens, stop taking SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).
- Lactic acidosis (lactic acid build up in the bloodstream)
- If you have a serious allergic reaction, including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes

These are all very serious side effects. If you have them, you may have had a serious reaction to SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea
- Flatulence
- Vomiting
- Constipation
- Metallic taste (An altered or impaired sense of taste)
- Abdominal pain and loss of appetite

Less frequent side effects:

- Low blood sugar
- Somnolence
- Diarrhoea,
- A low number of platelets in the blood (thrombocytopenia)
- A group of disorders that cause progressive scarring of lung tissue (interstitial lung disease)
- Joint pain (Arthralgia)
- Muscle pain (myalgia)
- Pain in extremity
- Back pain
- A disease or abnormality of a joint (arthropathy)
- Impaired or acute renal function
- Increase in white blood cell count

- Decrease of vitamin B12 and folic acid absorption
- Headache
- Dizziness
- Redness of the skin, either in a limited area or all over (Mild erythema)
- Upper abdominal pain
- Acute inflammation of the pancreas(pancreatitis)
- Itching
- Swelling under the skin
- Rash
- Raised or puffy areas of the skin that itch intensely
- Inflammation of blood vessels which can restrict blood flow
- Immune system attacks a thin layer of tissue below your other layer of skin (Bulleous pemphigoid)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA.

5) How to store SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA

Store all medicines out of reach of children.

- Store at or below 25 °C in the original package, protected from light and moisture.
- Do not remove the blisters from the carton until required for use.
- Remove your SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA from the blister only immediately prior to intake.
- Do not take SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA after the expiry date stated on the blister strips and carton.
- Return all unused or expired medicines to your pharmacist for safe disposal.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6) Contents of the pack and other information

What SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA contains

- The active ingredients is Sitagliptin and Metformin

SITAGLIPTIN/METFORMIN 50/500

Light pink to pink, Capsule shaped film-coated tablets debossed with “SC5” on one side.

SITAGLIPTIN/METFORMIN 50/850

Pink, Capsule shaped film-coated tablets debossed with “SC1” on one side.

SITAGLIPTIN/METFORMIN 50/1000

Brown to Reddish brown, Capsule shaped film-coated tablets debossed with “SC7” on one side.

The other ingredients are:

Hydroxypropyl cellulose, Anhydrous Calcium hydrogen phosphate, Crospovidone, Hydrogenated Castor Oil, Glycerol dibehenate, and Magnesium stearate.

Film coating

Ranbaxy Pharmaceuticals (Pty) Ltd
SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA
Sitagliptin Fumarate and Metformin Hydrochloride Tablets 50mg/500mg,
50mg/850mg and 50mg/1000mg



Opadry® Complete film coating system 20A540048 Pink,
Opadry® Complete film coating system 20A540053 Pink,
Opadry® Complete film coating system 20A565037 Brown,
Isopropyl Alcohol and Methylene Chloride

What SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA looks like and contents of the pack

SITAGLIPTIN/METFORMIN 50/500

Light pink to pink, Capsule shaped film-coated tablets debossed with "SC5" on one side.

SITAGLIPTIN/METFORMIN 50/850

Pink, Capsule shaped film-coated tablets debossed with "SC1" on one side.

SITAGLIPTIN/METFORMIN 50/1000

Brown to Reddish brown, Capsule shaped film-coated tablets debossed with "SC7" on one side.

The product can be supplied in pack sizes of 28's, 30's, 56's, 60's and 200's comprising of an HDPE bottle with silica gel desiccants and child resistant closure with induction seal liner.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd
14 Lautre Road, Stormill Ext.1
Roodepoort, 1724
South Africa

This leaflet was last revised in

Ranbaxy Pharmaceuticals (Pty) Ltd
SITAGLIPTIN/METFORMIN 50/500; 50/850; 50/1000 SUN PHARMA
Sitagliptin Fumarate and Metformin Hydrochloride Tablets 50mg/500mg,
50mg/850mg and 50mg/1000mg



08 July 2025

Registration numbers

SITAGLIPTIN/METFORMIN 50/500 SUN PHARMA - 57/21.2/0068.065

SITAGLIPTIN/METFORMIN 50/850 SUN PHARMA - 57/21.2/0069.066

SITAGLIPTIN/METFORMIN 50/1000 SUN PHARMA - 57/21.2/0070.067