

SITAPRIL M
Sitagliptin and Metformin hydrochloride Tablets
Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Distribution Category: Prescription Only Medicine or POM

What is in this leaflet?

1. What SITAPRIL M is and what it is used for
2. What you need to know before you take SITAPRIL M
3. How to take SITAPRIL M
4. Possible side effects
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1. What SITAPRIL M is and what it is used for

- SITAPRIL M is a prescription medicine that contains 2 prescription diabetes medicines, sitagliptin and metformin. SITAPRIL M can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- SITAPRIL M is not for people with type 1 diabetes.
- SITAPRIL M is not for people with diabetic ketoacidosis (increased ketones in your blood or urine).
- If you have had pancreatitis (inflammation of the pancreas) in the past, it is not known if you have a higher chance of getting pancreatitis while you take SITAPRIL M.
- It is not known if SITAPRIL M is safe and effective when used in children under 18 years of age.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems. High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

2. What you need to know before you Take SITAPRIL M

Do not take SITAPRIL M if:

- You have severe kidney problems.
- You are allergic to any of the ingredients in SITAPRIL M.

Symptoms of a serious allergic reaction to SITAPRIL M 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.

- You have diabetic ketoacidosis.

Warnings & Precautions

Lactic Acidosis

Metformin, one of the medicines in SITAPRIL M, can cause a rare but serious condition called lactic acidosis (a buildup of an acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.

Call your doctor right away if you have any of the following symptoms, which could 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 (not normal) 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 have other things that, combined with the metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance for getting lactic acidosis with SITAPRIL M 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 short-term "binge" drinking
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea.

Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids

- have surgery
- have a heart attack, severe infection, or stroke

The best way to keep from having a problem with 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 SITAPRIL M for a while if you have any of these things.

Pancreatitis (inflammation of the pancreas) which may be severe and lead to death. Certain medical problems make you more likely to get pancreatitis.

Before you start taking SITAPRIL M:

Tell your doctor if you have ever had

- pancreatitis
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

Stop taking SITAPRIL M and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

Heart failure.

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

Before you start taking SITAPRIL M, 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.

Before you take SITAPRIL M, tell your doctor if you:

- have or have had inflammation of your pancreas (pancreatitis).
- have severe kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- drink alcohol very often, or drink a lot of alcohol in short-term “binge” drinking.
- are going to get an injection of dye or contrast agents for an x-ray procedure; SITAPRIL M may need to be stopped for a short time. Talk to your doctor about when you should stop SITAPRIL M and when you should start SITAPRIL M again.
- See have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if SITAPRIL M will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breast-feeding or plan to breast-feed. It is not known if SITAPRIL M will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking SITAPRIL M.

SITAPRIL M & Other medicines

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SITAPRIL M may affect how well other drugs work and some drugs can affect how well SITAPRIL M 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.

3. How to use SITAPRIL M

Take SITAPRIL M exactly as your doctor tells you. Your doctor will tell you how many SITAPRIL M tablets to take and when you should take them.

- Your doctor may change your dose of SITAPRIL M if needed.
- Your doctor may tell you to take SITAPRIL M along with certain other diabetes medicines. Low blood sugar (hypoglycemia) can happen more often when SITAPRIL M is taken with certain other diabetes medicines.
- Take SITAPRIL M with meals to help to lower your chance of having an upset stomach.
- Do not break or cut SITAPRIL M tablets before swallowing. If you cannot swallow SITAPRIL M tablets whole, tell your doctor.
- Continue to take SITAPRIL M as long as your doctor tells you.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking SITAPRIL M.
- 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.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your haemoglobin A1C.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with SITAPRIL M.

If you take too much SITAPRIL M, call your doctor or hospital right away.

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 2 doses of SITAPRIL M at the same time.

You may need to stop taking SITAPRIL M for a short time. Call your doctor for instructions if you:

- are dehydrated (have lost too much body fluid). 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 procedure.

When your body is under some 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 problems and follow your doctor's instructions.

4. Possible side effects

Serious side effects have happened in people taking SITAPRIL M or the individual medicines in SITAPRIL M.

Low blood sugar (hypoglycemia). If you take SITAPRIL M 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 SITAPRIL M. Signs and symptoms of low blood sugar may include:

- Headache
- Drowsiness
- Irritability
- hunger
- dizziness
- confusion
- sweating
- feeling jittery
- weakness
- fast heart beat

Serious allergic reactions. If you have any symptoms of a serious allergic reaction, stop taking SITAPRIL M and call your doctor right away. Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

- Kidney problems, sometimes requiring dialysis.
- Joint pain. Some people who take medicines called DPP-4 inhibitors, one of the medicines in SITAPRIL M, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.
- Skin reaction. Some people who take medicines called DPP-4 inhibitors, one of the medicines in SITAPRIL M, 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 the breakdown of the outer layer of your skin (erosion). Your doctor may tell you to stop taking SITAPRIL M.

The most common side effects of SITAPRIL M include:

- stuffy or runny nose and sore throat
- upper respiratory infection
- low blood sugar (hypoglycemia) when used in combination with certain medications, such as a sulfonylurea or insulin.
- gas, upset stomach, indigestion
- nausea and vomiting
- headache

- weakness
- diarrhea

Taking SITAPRIL M 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.

SITAPRIL M may have other side effects, including swelling of the hands or legs. Swelling of the hands and legs can happen if you take SITAPRIL M in combination with rosiglitazone. Rosiglitazone is another type of diabetes medicine.

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

Tell your doctor if you have any side effect that bothers you, is unusual, or does not go away. Call your doctor for medical advice about side effects.

5. How to store SITAPRIL M

- Store SITAPRIL below 30°C.
- Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What SITAPRIL M contains:

Active substances are:

SITAPRIL M 50/500 (Sitagliptin 50 mg and Metformin Hydrochloride 500 mg Tablets)

Each film coated tablet contains:

Sitagliptin Phosphate Monohydrate USP

Equivalent to Sitagliptin.....50 mg

Metformin Hydrochloride USP....500 mg

Colour: Red Iron Oxide, Yellow Iron Oxide & Titanium Dioxide

Excipients.....q.s.

SITAPRIL M 50/1000 (Sitagliptin 50 mg and Metformin Hydrochloride 1000 mg Tablets)

Each film coated tablet contains:

Sitagliptin Phosphate Monohydrate USP

Equivalent to Sitagliptin.....50 mg

Metformin Hydrochloride USP....1000 mg

Colour: Red Iron Oxide, Yellow Iron Oxide & Titanium Dioxide

Excipients.....q.s.

List of Excipients:

SITAPRIL M 50/500 (Sitagliptin 50 mg and Metformin Hydrochloride 500 mg Tablets)
Microcrystalline Cellulose, Anhydrous Dibasic Calcium Phosphate (Calipharm A), Povidone, Croscarmellose Sodium, Sodium Stearyl Fumarate, Opadry 03B84681 Pink and Purified Water.

SITAPRIL M 50/1000 (Sitagliptin 50 mg and Metformin Hydrochloride 1000 mg Tablets)
Microcrystalline Cellulose, Anhydrous Dibasic Calcium Phosphate (Calipharm A), Povidone, Croscarmellose Sodium, Sodium Stearyl Fumarate, Opadry 03B565053 Brown and Purified Water.

What SITAPRIL M looks like and contents of the pack

SITAPRIL M 50/500 (Sitagliptin 50 mg and Metformin Hydrochloride 500 mg Tablets)
Light pink colored, capsule-shaped, film-coated tablets debossed SM1 on one side and plain on other side.

SITAPRIL M 50/1000 (Sitagliptin 50 mg and Metformin Hydrochloride 1000 mg Tablets)
Reddish brown colored, capsule-shaped, film coated tablets debossed SM2 on one side and plain on other side.

10 tablets in Alu-Alu blister pack, 3 such blister in a printed carton along with Pack Insert.

MANUFACTURING AUTHORISATON HOLDER AND MANUFACTURER

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For any information about this medicinal product, please contact the Manufacturing Authorisation Holder.

DATE OF PUBLICATION OR REVISION

Dec, 2020.