

**Sitapril Tablets**  
**(Sitagliptin Tablets USP 25 mg / 50mg / 100 mg)**

**Patient Information Leaflet**

**Read all of this leaflet carefully before you start taking 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, pharmacist, or nurse.
- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.
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**Distribution Category:** Prescription Only Medicine or POM

**What is in this leaflet?**

1. What Sitapril is and what it is used for
2. What you need to know before you take Sitapril
3. How to take Sitapril
4. Possible side effects
5. How to store Sitapril
6. Contents of the pack and other information

**1. What SITAPRIL is and what it is used for**

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SITAPRIL is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

SITAPRIL is not for people with type 1 diabetes.

SITAPRIL 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.

It is not known if SITAPRIL 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**

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Do not take SITAPRIL if:

- you are allergic to any of the ingredients in SITAPRIL.

Symptoms of a serious allergic reaction to SITAPRIL 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.

**Before you start taking SITAPRIL, tell your doctor if you have ever had:**

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

Stop taking SITAPRIL 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 your heart does not pump blood well enough.

Before you start taking SITAPRIL, 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.

### **Pregnancy & Breast feeding**

- Are pregnant or plan to become pregnant. It is not known if SITAPRIL 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 will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking SITAPRIL.

### **Other medicine with Sitapril**

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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 take SITAPRIL**

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- Take SITAPRIL 1 time each day exactly as your doctor tells you.
- You can take SITAPRIL with or without food.
- Your doctor may do blood tests from time to time to see how well your kidneys are working. Your doctor may change your dose of SITAPRIL based on the results of your blood tests.
- Your doctor may tell you to take SITAPRIL along with other diabetes medicines. Low blood sugar can happen more often when SITAPRIL is taken with certain other diabetes medicines.
- 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 conditions and follow your doctor's instructions.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking SITAPRIL.
- 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.

*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 two doses of SITAPRIL at the same time.

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

### **4. Possible side effects**

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Serious side effects have happened in people taking SITAPRIL.

- Low blood sugar (hypoglycemia). If you take SITAPRIL 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. 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 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 like SITAPRIL, 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 like SITAPRIL 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.

The most common side effects of SITAPRIL include upper respiratory infection, stuffy or runny nose and sore throat, and headache.

SITAPRIL may have other side effects, including stomach upset and diarrhea, swelling of the hands or legs, when SITAPRIL is used with rosiglitazone. Rosiglitazone is another type of diabetes medicine.

These are not all the possible side effects of SITAPRIL. 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**

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

## **6. Contents of the pack and other information**

### **What SITAPRIL contains:**

The active ingredient is:

#### **Sitapril 25 (Sitagliptin Tablets USP 25 mg)**

Each film coated tablet contains:

Sitagliptin Phosphate Monohydrate USP  
equivalent to Sitagliptin (25 mg)

- Colour: Red Iron Oxide, Yellow Iron Oxide & Titanium Dioxide
- Excipients.....q.s.

**Sitapril 50 (Sitagliptin Tablets USP 50mg)**

Each film coated tablet contains:

Sitagliptin Phosphate Monohydrate USP  
equivalent to Sitagliptin (50 mg)

- Colour: Red Iron Oxide, Yellow Iron Oxide & Titanium Dioxide
- Excipients.....q.s.

**Sitapril 100 (Sitagliptin Tablets USP 100 mg)**

Each film coated tablet contains:

Sitagliptin Phosphate Monohydrate USP  
equivalent to Sitagliptin (100 mg)

- Colour: Red Iron Oxide, Yellow Iron Oxide & Titanium Dioxide
- Excipients.....q.s.

**List of Excipients:**

**SITAPRIL 25 (Sitagliptin Tablets USP 25 mg)**

Microcrystalline Cellulose  
Anhydrous Dibasic Calcium Phosphate  
Croscarmellose Sodium  
Magnesium Stearate  
Sodium Stearyl Fumarate  
Instacoat Aqua II A02G10250 Peach  
Purified water

**SITAPRIL 50 (Sitagliptin Tablets USP 50 mg)**

Microcrystalline Cellulose  
Anhydrous Dibasic Calcium Phosphate  
Croscarmellose Sodium  
Magnesium Stearate  
Sodium Stearyl Fumarate  
Instacoat Aqua II A02G10249 Beige  
Purified water

**SITAPRIL 100 (Sitagliptin Tablets USP 100 mg)**

Microcrystalline Cellulose  
Anhydrous Dibasic Calcium Phosphate  
Croscarmellose Sodium  
Magnesium Stearate  
Sodium Stearyl Fumarate  
Instacoat Aqua II A02G10251 Beige  
Purified water

## What SITAPRIL looks like and contents of the pack

### Sitapril 25 (Sitagliptin Tablets USP 25 mg):

Pink colored, round, film coated tablets debossed 'ST1' on one side and plain on other side

### Sitapril 50 (Sitagliptin Tablets USP 50 mg):

Light beige colored, round, film coated tablets debossed 'ST2' on one side and plain on other side.

### Sitapril 100 (Sitagliptin Tablets USP 100 mg):

Beige colored, round, film coated tablets debossed 'ST3' 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

Manufacturing Authorisation Holder	Manufacturer
Ajanta Pharma Limited Ajanta House, Charkop Kandivli (West) Mumbai - 400 067 India. Tel : +91-22-6606 1000 Fax : (0091) 22-66061200/ 300 Email : info@ajantapharma.com	Ajanta Pharma Limited B-4-5-6, MIDC Industrial Area Paithan, Aurangabad, 431148 Dist: Aurangabad Maharashtra, India. Tel : +91-2431-664000 Fax : +91-2431-664100

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

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