SITAVIO FILM COATED TABLETS

Sitagliptin 50mg, 100mg

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What Sitavio is used for

Sitavio is a tablet that contains 50 or 100 mg of sitagliptin as the active ingredient.

- Sitavio helps to improve the levels of insulin after a meal.
- Sitavio decreases the amount of sugar made by the body.
- Sitavio works when blood sugar is high, especially after a meal. This is when the body needs the greatest amount of help in lowering blood sugar. Sitavio also lowers blood sugar between meals.
- Sitavio by itself is unlikely to cause low blood sugar (hypoglycemia) because it does not work when your blood sugar is low.

How Sitavio works

Sitavio is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM.

Before you use Sitavio

– *When you must not use it*

Do not take Sitavio:

- If you have allergic toward any of the component in Sitavio.

– *Before you start to use it*

Tell your doctor or pharmacist if you are allergic to any medicines or if have had:

- Type 1 diabetes
- diabetic ketoacidosis (increased ketones in the blood or urine)
- any kidney problems, or any past or present medical problems
- an allergic reaction to Sitavio
- gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis.

– *Taking other medicines*

Sitavio may be taken with most medicines. Tell your doctor about all the medicines you take. This includes prescription and non-prescription medicines, and herbal supplements.

In particular, tell your doctor:

- if you are taking digoxin (a medicine used to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with Sitavio.

How to use Sitavio

– *How much to use*

Take Sitavio exactly as your doctor has prescribed. The recommended dose is to take:

- one 100 mg tablet
- once a day
- by mouth, with or without food

If you have kidney problems, your doctor may prescribe lower doses.

Your doctor may prescribe Sitavio along with certain other medicines that lower blood sugar.

– *When to use it*

May be taken with or without food. Take as directed by your doctor or pharmacist.

– *How long to use it*

Sitavio should be taken as long as your doctor advised you to do so that you can continue to help control your blood sugar.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and weight loss program while taking Sitavio.

– *If you forget to use it*

If you miss a dose, take the missed dose as soon as you remember. However, if it's almost time for the next dose, skip the missed dose and continue the regular dosing schedule. Do not take a double dose to make up for a missed one.

– *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

– *Things you must do*

Follow your doctor's instruction when you are taking Sitavio.

Tell all the doctors, dentists and pharmacists treating you that you are taking Sitavio.

You should promptly report to physician if you become pregnant while taking Sitavio.

– *Things you must not do*

Do not stop taking this medicine or change the dosing regimen without instruction from your doctor. Do not give this medication to anyone else, even if they have the same condition as you.

– *Things to be careful of*

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Sitavio. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Sitavio and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Cases of a skin reaction called bullous pemphigoid that can require treatment in a hospital have been reported in patients receiving Sitavio. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking Sitavio.

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Use in children
Sitavio is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. Sitavio has not been studied in children younger than 10 years of age.

Use in the elderly
In studies, Sitavio worked well in and was well-tolerated by older adult patients. No dosage adjustment is necessary based on age.

Use in pregnancy and breast-feeding
Women who are pregnant or plan to become pregnant should consult with their doctor before taking Sitavio. Sitavio is not recommended for use during pregnancy.

It is not known if Sitavio passes into breast milk. You should not use Sitavio if you are breast-feeding or plan to breast- feed.

Driving and using machines
There is no information to suggest that Sitavio affects your ability to drive a car or operate machinery.

Side Effects

Like all medicines, Sitavio can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice anything else that making you feel unwell.
Additional side effects have been reported in general use with Sitavio, by itself and/or with other diabetes medicines:

• Reduced number of platelets
• Allergic reactions, which may be serious, including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking Sitavio and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.

- low blood sugar with symptoms (hypoglycemia)
- Headache
- Dizziness
- Upper respiratory infection
- Stuffy or runny nose and sore throat
- Constipation
- Vomiting
- Inflammation of the pancreas
- Itching
- Blisters
- Joint pain
- Muscle aches
- Back pain
- Arm or leg pain
- Kidney problems

Tell your doctor or pharmacist if you develop any unusual side effect, or if any known side effect does not go away or gets worse.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Sitavio

– *Storage*
Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister strip after EXP. The expiry date refers to the last day of that month.

Store below 30ºC.

– *Disposal*
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

– *What it looks like*

Sitavio 50mg Film Coated Tablets
Beige, round shaped film coated tablet debossed with 'C 33' on one side of the tablet and plain on the other side

Sitavio 100mg Film Coated Tablets
Beige, round shaped film coated tablet debossed with 'C 32' on one side of the tablet and plain on the other side

The tablets are available in 1 x 10's, 3 x 10's, 6 x 10's, 10 x 10's, 50 x10's, 100 x 10's blister form packed in the outer carton. Not all pack sizes will be marketed.

– *Ingredients*
– Active ingredient
The active substance of Sitavio is Sitagliptin Phosphate Monohydrate 64.250mg or 128.500mg (equivalent to 50mg or 100 mg, respectively).

– Inactive ingredient
Tablet core:

- Microcrystalline Cellulose
- Anhydrous Dibasic Calcium Phosphate
- Croscarmellose Sodium
- Sodium Stearyl Fumarate
- Magnesium Stearate

Film coat

- Opadry II Complete Film Coating System 85F17438 Beige

– *MAL number*

- Sitavio 50mg Film Coated Tablets
  MAL22126053AZ

- Sitavio 100mg Film Coated Tablets
  MAL22126054AZ

Manufacturers
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