

SITACORD 50 and 100

(Sitagliptin Film Coated Tablets 50mg & 100mg)

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Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What Sitacord 50 & 100 is used for

Sitacord 50 & 100 (Sitagliptin phosphate) is a tablet that contains 50, or 100 mg of sitagliptin as the active ingredient.

- Sitacord 50 & 100 helps to improve the levels of insulin after a meal.
- Sitacord 50 & 100 decreases the amount of sugar made by the body.
- Sitacord 50 & 100 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. Sitacord 50 & 100 also

lowers blood sugar between meals.

Sitacord 50 & 100 by itself is unlikely to cause low blood sugar (hypoglycemia) because it does not work when your blood sugar is low.

How Sitacord 50 & 100 works

Sitacord 50 & 100 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.

Why has my doctor prescribed Sitacord 50 & 100?

Your doctor has prescribed Sitacord 50 & 100 to help lower your blood sugar, which is too high because of your type 2 diabetes. JANUVIA can be used alone or in combination with certain other medicines that lower blood sugar, along with a recommended diet and exercise program.

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.

The main goal of treating diabetes is to lower your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness, and amputation.

High blood sugar can be lowered by diet and exercise, and by certain medicines.

Before you use Sitacord 50 & 100

- When you must not use it

Do not take Sitacord 50 & 100 if you are allergic to any of the ingredients in Sitacord 50 & 100.

- Before you start use it

Tell your doctor if you have or 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 Sitacord 50 & 100.
- 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

Sitacord 50 & 100 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 heart beat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with Sitacord 50 & 100

How to take Sitacord 50 & 100

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- How much to take and when to take it

Take Sitacord 50 & 100 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 Sitacord 50 & 100 along with certain other medicines that lower blood sugar.

- How long to take it

Continue to take Sitacord 50 & 100 as long as your doctor prescribes it so 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 Sitacord 50 & 100.

- If you forget to take it

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 Sitacord 50 & 100.

- If you use too much (overdose)

If you take more than the prescribed dosage of Sitacord 50 & 100, contact your doctor immediately.

While you are taking it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Sitacord 50 & 100.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not give Sitacord 50 & 100 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Sitacord 50 & 100.

Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Sitacord 50 & 100 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 Sitacord 50 & 100. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking Sitacord 50 & 100.

Use in children

Sitacord 50 & 100 is not effective in children and adolescents 10 to 17 years of

age with type 2 diabetes. Sitacord 50 & 100 has not been studied in children younger than 10 years of age.

Use in the elderly

In studies, Sitacord 50 & 100 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 Sitacord 50 & 100. Sitacord 50 & 100 is not recommended for use during pregnancy.

It is not known if Sitacord 50 & 100 passes into breast milk. You should not use Sitacord 50 & 100 if you are breast-feeding or plan to breast-feed.

Can I drive or operate machinery while using Sitacord 50 & 100?

There is no information to suggest that Sitacord 50 & 100 affects your ability to drive a car or operate machinery.

Side effects

Like all prescription medicines, Sitacord 50 & 100 may cause side effects. Side effects usually were mild and did not cause patients to stop taking Sitacord 50 & 100. The side effects reported in patients treated with Sitacord 50 & 100 were similar to side effects in patients treated with a tablet containing no medication (a placebo).

When Sitacord 50 & 100 is used in combination with a sulfonylurea medicine or with

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insulin, low blood sugar with symptoms (hypoglycemia) due to the sulfonylurea or insulin can occur. Lower doses of the sulfonylurea medicine or insulin may be required.

When Sitacord 50 & 100 was used in combination with insulin, the following additional side effects were reported:

- Flu
- Headache

When Sitacord 50 & 100 and metformin were started together, the following side effects were reported:

- Diarrhea
- Indigestion
- Flatulence
- Vomiting
- Headache

When Sitacord 50 & 100 and pioglitazone were started together, the side effect of decreased blood sugar measurements without symptoms of hypoglycemia was reported.

When Sitacord 50 & 100 was used in combination with metformin and rosiglitazone, the following side effects were reported:

- Headache
- Low blood sugar with symptoms (hypoglycemia)
- Diarrhea
- Upper respiratory infection
- Nausea
- Cough
- Fungal skin infection
- Swelling of the hands or legs
- Vomiting

Additional side effects have been reported in general use with Sitacord 50 & 100 by itself

and/or with other diabetes medicines:

- 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 Sitacord 50 & 100 and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.
- Inflammation of the pancreas.
- Kidney problems (sometimes requiring dialysis).
- Upper respiratory infection.
- Stuffy or runny nose and sore throat.
- Constipation.
- Vomiting.
- Headache.
- Joint pain.
- Muscle aches.
- Arm or leg pain.
- Back pain.
- Itching.
- Blisters.
- Reduced number of platelets.

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 Sitacord 50 & 100:

- Storage

Store below 30°C.

Keep Sitacord 50 & 100 and all medicines safely away from children.

- Disposal

How long should I keep my medicine?

Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

Product Description

- What it looks like

Sitacord 50: Light beige color, round, biconvex, film coated tablet, debossed with “114” on one side and plain on other side.

Sitacord 100: Beige color, round, biconvex, film coated tablet, debossed with “113” on one side and plain on other side.

- Ingredients

- Active ingredient(s)

Sitagliptin Phosphate Anhydrous equivalent to Sitagliptin

- Inactive ingredients

Tablet core:

Microcrystalline Cellulose PH 200 LM
Dicalcium Phosphate Anhydrous Di- Cafos A 150
Croscarmellose Sodium (ACDISOL)
Magnesium stearate
Sodium Stearyl Fumarate

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Film-coating

Polyvinyl Alcohol-Part.

Hydrolyzed (E1203)

Titanium dioxide (E171)

Macrogol / PEG (E1521)

Talc (E553b)

Iron oxide yellow (E172)

Iron Oxide Red (E172)

- *MAL number(s)*:

Sitacord 50:

Sitacord 100:

Manufacturer:

Name and address

Intas Pharmaceuticals Limited.

Plot No 5-14, Pharmez,

Near Village Matoda,

Sarkhej-Bavla National

Highway No. 8-A,

Sanand Taluka

Ahmedabad, Gujarat

IN 382213, INDIA.

Product Registration Holder:

Accord Healthcare Sdn. Bhd.

Suite 12A-15, Level 12A,

Wisma Zelan No 1 Jalan Tasik

Permaisuri 2, Bandar Tun

Razak, 56000 Kuala Lumpur,

Malaysia.

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12/04/2023

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