

JIMANDIN FILM COATED TABLETS

Sitagliptin (25mg, 50mg, 100mg)

What is in this leaflet

1. What JIMANDIN is used for
2. How JIMANDIN works
3. Before you use JIMANDIN
4. How to use JIMANDIN
5. While you are using it
6. Side effects
7. Storage and Disposal of JIMANDIN
8. Product description
9. Manufacturer and Product registration holder
10. Date of revision
11. Serial number

What JIMANDIN is used for

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

How JIMANDIN works

- JIMANDIN contains the active substance sitagliptin which 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 adult patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM.

Why has my doctor prescribed JIMANDIN?

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

Before you use JIMANDIN

When you must not use it

Do not take JIMANDIN:

- If you are allergic (hypersensitive) to sitagliptin or any other ingredients of this medicine.

Before you start to use it

Talk to your doctor or pharmacist before taking JIMANDIN 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 JIMANDIN
- 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.

Pregnancy and breast-feeding

- 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. You should not take this medicine during pregnancy.
- It is not known if this medicine passes into breast milk. You should not take this medicine if you are breast-feeding or plan to breast-feed.

Taking other medicines

JIMANDIN 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 taking with JIMANDIN.

How to use JIMANDIN

How much to use

Take JIMANDIN exactly as your doctor has prescribed. The

recommended dose is one 100 mg tablet, once a day, by mouth.

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

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

When to use it

- Always take this medicine exactly as your doctor has told you.
- You can take this medicine with or without food.

How long to use it

- Continue to take this medicine 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 recommended while taking JIMANDIN.

If you forget to use it

- If you forget to take a tablet, take one 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 to make up for a forgotten dose.

If you use too much (overdose)

- If you take more than the prescribed dosage of this medicine, contact your doctor immediately.

While you are using 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 JIMANDIN.
- 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.

JIMANDIN FILM COATED TABLETS

Sitagliptin (25mg, 50mg, 100mg)

- This medicine has been prescribed for you only. Do not pass it on to others, even if their signs of illness are the same as yours.

Things to be careful of

- Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving JIMANDIN. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking JIMANDIN 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 JIMANDIN. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking JIMANDIN.

Use in children

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

Use in the elderly

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

Driving and using machines

There is no information to suggest that JIMANDIN affects your ability to drive a car or operate machinery.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In studies, side effects usually were mild and did not cause patients to stop taking JIMANDIN. The side effects reported in patients treated with a tablet containing no medication (a placebo).

When JIMANDIN is used in combination with a sulfonylurea medicine or with 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 JIMANDIN was used in combination with insulin, the following additional side effects were reported:

- Flu
- Headache

When JIMANDIN and metformin were started together, the following side effects were reported:

- Diarrhea
- Indigestion
- Flatulence
- Vomiting
- Headache

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

When JIMANDIN 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 JIMANDIN, 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 JIMANDIN 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 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) of Vaccines (AEFI)]

Storage and Disposal of JIMANDIN

Storage

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

Disposal

- Do not use this medicine after the expiry date stated on the carton and blister after "EXP".
- The expiry date refers to the last day of that month
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

What it looks like

- JIMANDIN 25mg: Yellow, round biconvex film coated tablets with diameter approximately 6mm.
- JIMANDIN 50mg: Pale red, round, biconvex film coated tablets, with diameter approximately 8mm.

JIMANDIN FILM COATED TABLETS

Sitagliptin (25mg, 50mg, 100mg)

- JIMANDIN 100mg: Light brown, round, biconvex film coated tablets with diameter approximately 10.3mm.

Ingredients

Active ingredient

The active substance is sitagliptin. Each tablet contains sitagliptin phosphate monohydrate, equivalent to 25mg, 50 mg or 100mg sitagliptin.

Inactive ingredients

The other ingredients are:

- Tablet core: Microcrystalline cellulose (E460), Calcium hydrogen phosphate, anhydrous, Croscarmellose sodium, Magnesium stearate, Sodium stearyl fumarate.
- Coating: Opadry White (85F18422) [Polyvinyl alcohol (E1203), Titanium dioxide (E171), Macrogol (E1521), Talc (E553b)], for 25mg tablet Iron oxide yellow (E172), for 50mg tablet Iron oxide red (E172), for 100mg tablet Iron oxide yellow (E172) and Iron oxide red (E172).

MAL number:

- JIMANDIN 25mg Film Coated Tablets MAL.....AZ
- JIMANDIN 50mg Film Coated Tablets MAL.....AZ
- JIMANDIN 100mg Film Coated Tablets MAL.....AZ

Manufacturer

MEDOCHEMIE (FAR EAST) LTD-
(Oral Facility)
40, VSIP II Street 6, Vietnam-Singapore Industrial park II, Binh Duong Industry-Service, Urban Complex, Hoa Phu Ward, Thu Dau Mot Town, Binh Duong Province VIETNAM

Product registration holder

KOMEDIC SDN BHD
4 Jalan PJS 11/14, Bandar Sunway,
46150 Petaling Jaya, Selangor D.E.

Date of revision

08/10/2024

Serial Number

NPRA(R2)24/054