

JAVEXA FILM COATED TABLET

Sitagliptin (50mg, 100mg)

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What JAVEXA is used for

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

- JAVEXA helps to improve the levels of insulin after a meal.
- JAVEXA decreases the amount of sugar made by the body.
- JAVEXA 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. JAVEXA also lowers blood sugar between meals.
- JAVEXA by itself is unlikely to cause low blood sugar (hypoglycemia) because it does not work when your blood sugar is low.

How JAVEXA works

JAVEXA 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 JAVEXA

- When you must not use it
Do not take JAVEXA if you are allergic to any of the ingredients in JAVEXA.
- Before you start to 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 JAVEXA
 - 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 lactation

Women who are pregnant or plan to become pregnant should consult with their doctor before taking JAVEXA. JAVEXA is not recommended for use during pregnancy.

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

Taking other medicines

JAVEXA 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 JAVEXA.

How to use JAVEXA

How much to use

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 JAVEXA along with certain other medicines that lower blood sugar.

When to use it

Take JAVEXA exactly as your doctor has prescribed.

How long to use it

Continue to take JAVEXA 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 JAVEXA.

If you forget to use 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 JAVEXA.

If you use too much (overdose)

If you take more than the prescribed dosage of JAVEXA, contact your doctor immediately.

While you are using JAVEXA

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 JAVEXA.

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

Use in children

JAVEXA is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. JAVEXA has

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not been studied in children younger than 10 years of age.

Use in the elderly

In studies, JAVEXA 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 JAVEXA affects your ability to drive a car or operate machinery.

Side Effects

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

When JAVEXA 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 JAVEXA was used in combination with insulin, the following additional side effects were reported:

- Flu
- Headache

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

- Diarrhea
- Indigestion
- Flatulence
- Vomiting
- Headache

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

When JAVEXA 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 JAVEXA, 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 JAVEXA 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 npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of JAVEXA

- Storage

Keep out of the reach of children.
Store below 30°C.

- 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

JAVEXA FILM COATED TABLET 50MG:

Film-coated, round, biconvex, orange tablets, one side engraving "50".

JAVEXA FILM COATED TABLET 100MG:

Film-coated, round, biconvex, orange tablets, one side engraving "100".

- Ingredients

- Active ingredient:

Sitagliptin Hydrochloride Monohydrate

- Inactive ingredients:

Tablet core:
Calcium Phosphate Anhydrous, Microcrystalline Cellulose 12, Croscarmellose Sodium, Sodium Stearyl Fumarate, Magnesium Stearate

Film coating:

Polyvinyl Alcohol, Macrogol 4000, Titanium Dioxide, Talc, Red Iron Oxide (E172), Yellow Iron Oxide (E172)

- MAL number:

JAVEXA FILM COATED TABLET 50MG:

MAL*****

JAVEXA FILM COATED TABLET 100MG:

MAL*****

Manufacturer

Adamed Pharma S.A.
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Product Registration Holder

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Date of Revision

25/06/2026

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