

Drug Information Sheet ("Kusuri-no-Shiori")

621951001

Revised: 06/2011

Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan.

In deciding to use a medicine, the risk (side effects) of taking the medicine must be weighed against the benefit (effects) it will do. The patient's cooperation is indispensable here.

Brand name : JANUVIA Tablets 50mg

Active ingredient : Sitagliptin phosphate hydrate

Dosage form : faintly reddish yellow tablet, ϕ : 7.9 mm, thickness: 3.3 mm

Printings on wrapping : JANUVIA 50mg, ジャヌビア 50mg, MSD 112



Effects of this medicine

This medicine inhibits enzyme that degrades incretin, blood glucose stabilizing substance. It consequently enhances insulinotropic action and effect of lowering glucagon level in state of hyperglycemia to improve blood glucose control.

It is usually used to treat type 2 diabetes.

Before using this medicine, tell your doctor/pharmacist

- If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.
If you are a patient with ketosis, diabetic coma or precoma stage, type 1 diabetes, renal dysfunction, infection, injury, pituitary gland disorder, adrenal gland disorder, insufficient diet, or are in pre/postoperative period, or are debilitated.
If you exercise intensely or drink a lot of alcohol.
- If you are pregnant or breastfeeding.
- If you are using any other prescription or nonprescription (OTC) medicine. (It is important to reduce the risk of drug interactions.)

Dosage regimen (proper use of this medicine)

- **Your dosage regimen is:**◀◀ :order of your doctor▶▶
- General dosage regimen: For patients with normal renal function or mild renal dysfunction, for adults, take 1 tablet (50 mg of the active ingredient) at a time, once a day. If the dose seems to be insufficient, it may be increased up to 2 tablets (100 mg of the active ingredient) at a time, once a day, adequately monitoring the condition. Strictly follow the instructions of your doctor/pharmacist. For patients with moderate renal dysfunction, for adults, take 25 mg of the active ingredient at a time, once a day. If the dose seems to be insufficient, it may be increased up to 1 tablet (50 mg of the active ingredient) at a time, once a day, adequately monitoring the condition. Strictly follow the instructions of your doctor/pharmacist.
- Missed dose: Take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. DO NOT take double doses to make up for the missed dose.
- Overdose: If you took too much of the medicine (more than ordered), check with your doctor/pharmacist.
- Others: Do not stop taking the medicine without the instructions of your doctor.

Precautions while using this medicine

- Strictly follow diet and exercise therapy instructed by your doctor.
- Pay close attention that the medicine may cause hypoglycemia.
- In case hypoglycemia occurs, take food or drink that contains enough amount of sugar (sugar, glucose, refreshing drink, etc.). If you are taking the medicine concomitantly with an α -glucosidase inhibitor (drugs which delay absorption of sugar), ingest glucose in case of any hypoglycemic symptoms occur.

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Side effects of this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: hypoglycemia, constipation, etc.

In rare cases, symptoms described below may be the sign of side effects indicated in brackets []. If they occur, stop taking your medicine and check with your doctor immediately.

- breathing difficulty, hives, swelling around eyes and lips [anaphylactic reaction]
- fever, erythema, bloodshot eyes [Stevens-Johnson syndrome, dermatitis exfoliativa]
- chills, craving for food, tremor in limbs [hypoglycemia]
- loss of appetite, general malaise, yellowness in skin or conjunctiva [hepatic dysfunction, jaundice]
- decreased urine output, general edema, malaise [acute renal failure]
- severe pain in the upper abdomen, back pain, nausea [acute pancreatitis]
- fever, dry cough, breathing difficulty [interstitial pneumonia]

Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.

Storage and other information

- Keep out the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For doctor use only: Day Month Year

For further information, ask your doctor/pharmacist. "Kanjamuke Iyakuin Guide" and Japanese package insert information (for medical professionals) is available on the website of Pharmaceuticals and Medical Devices Agency.