

What is in this leaflet

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

What Alvilda is used for

Each Alvilda tablet contains 50 mg of the active substance vildagliptin.

Alvilda is a medicine used to treat patients with type 2 diabetes whose condition cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics.

Type 2 diabetes develops if the body does not produce enough insulin or if the insulin that your body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance that helps to lower the level of sugar in your blood, especially after meals. Glucagon is a substance that triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

How Alvilda works

Alvilda works by making the pancreas produce more insulin and less glucagon. Alvilda helps to control the blood sugar level.

Your doctor will prescribe Alvilda either alone or in combination with other antidiabetics depending on your condition.

It is important that you continue to follow the diet and/or exercise recommended to you while you are on treatment with Alvilda.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use Alvilda

Follow all instructions given to you by your doctor or pharmacist carefully, even

if they differ from the information contained in this leaflet.

- When you must not use it
- If you are allergic (hypersensitive) to vildagliptin or any of the other ingredients of Alvilda.

Pregnant women

Tell your doctor if you are pregnant, if you think you might be pregnant, or if you are planning to become pregnant. Your doctor will discuss with you the potential risk of taking Alvilda during pregnancy.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

Breast-feeding mothers

Do not breast-feed during treatment with Alvilda.

Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

- Before you start to use it

Take special care with Alvilda

- If you are pregnant or plan to become pregnant.
- If you are breast-feeding.
- If you have kidney problems.
- If you have liver problems.
- If you are suffering from heart failure, your doctor will decide whether or not to prescribe Alvilda depending on the degree of your condition.
- Alvilda is not a substitute for insulin. You should therefore neither receive Alvilda for the treatment of type 1 diabetes (i.e. your body does not produce insulin at all) nor for the treatment of a condition called diabetic ketoacidosis.

If any of these apply to you, tell your doctor before you take Alvilda.

Monitoring your Alvilda treatment

Your doctor should ensure that the following tests are performed:

- Blood and urine tested for sugar regularly
- Check how your liver functions:
 - at start of treatment

- every 3 months during the first year of treatment and regularly thereafter
- if your doctor has told you to stop treatment with Alvilda because of liver problems you should never start taking Alvilda again.

Alvilda and older people

Alvilda can be used by elderly patients.

Alvilda in children/adolescents

There is no information available on the use of Alvilda in children and adolescents (age below 18 years). The use of Alvilda in these patients is therefore not recommended.

Important information about some of the ingredients of Alvilda

Alvilda contains an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking Alvilda.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Remember also those not prescribed by a doctor.

How to use Alvilda

Follow all instructions given to you by your doctor and pharmacist carefully, even if they differ from the ones given in this leaflet. Do not take more Alvilda than your doctor has prescribed.

- How much to use

Your doctor will tell you exactly how many tablets of Alvilda to take.

The usual dose of Alvilda is 50 mg or 100 mg a day. The 50 mg dose should be taken as 50 mg once a day (morning). The 100 mg dose should be taken as 50 mg twice a day (morning and evening). Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Your doctor will prescribe Alvilda either alone or in combination with other antidiabetics, depending on your condition.

- When to use it

Alvilda should be taken in the morning (50mg once a day) or in the morning and evening (50mg twice daily). Alvilda can be taken with or without a meal. The tablets should be swallowed whole with a glass of water.

- How long to use it

Continue taking Alvilda every day for as long as your doctor tells you. You may have to stay on this treatment for a long period of time. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If your doctor has told you to stop treatment with Alvilda because of liver problems you should never start taking Alvilda again.

If you have questions about how long to take Alvilda, talk to your doctor.

- If you forget to use it

If you forget to take Alvilda, take it as soon as you remember. Then take your next dose at the usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

- If you use too much (overdose)

If you have accidentally taken too many tablets, or if someone else has taken your medicine, talk to a doctor straight away. You may require medical attention. Show the doctor the pack if possible.

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 Alvilda.

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 take any new medicines without consulting your doctor.

Do not give Alvilda to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Patients experiencing dizziness should avoid driving vehicles or using machines.

Side effects

Alvilda can have some side effects in some people. Some patients have experienced the following side effects while taking Alvilda or in combination with another antidiabetic medication:

Some symptoms need immediate medical attention

You should stop taking Alvilda and see your doctor immediately if you experience the following symptoms:

- Swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction called 'angioedema').
- Yellow skin and/or eyes, nausea, loss of appetite, light-colored urine (possible symptoms of liver problems).
- Severe upper stomach pain (possible symptom of inflamed pancreas).
- Headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery (possible symptoms of low level of sugar in the blood known as 'hypoglycemia')

Other side effects

Common side effects

Uncommon side effects

Some patients have had the following side effects while taking Alvilda alone:

- Common: Dizziness.
- Uncommon: Headache, constipation, swollen hands, ankles or feet (edema).

Some patients have had the following side effects while taking Alvilda and metformin:

- Common: Trembling, headache, dizziness.

Some patients have had the following side effects while taking Alvilda and a sulphonylurea:

- Common: Trembling, headache, dizziness, weakness

Some patients have had the following side effects while taking Alvilda and a glitazone:

- Common: Weight increase, swollen hands, ankles or feet (edema).
- Uncommon: Headache.

Some patients have had the following side effects while taking Alvilda and insulin (with or without metformin):

- Common: Headache, chills, nausea, decreased blood sugar, heartburn.
- Uncommon: Diarrhea, flatulence.

Some patients have had the following side effects while taking Alvilda with metformin and a sulphonylurea:

- Common: Dizziness, trembling, weakness, excessive sweating,

If any of these affects you severely, tell your doctor.

Some patients have experienced other side effects while taking Alvilda alone or in combination with another antidiabetic medication:

- Itchy rash, areas of peeling skin or blisters, joint pain.

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Alvilda

- Storage

Do not store above 30°C. Protect from moisture.

- 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

ALVILDA is white to off-white, round, flat, beveled edge uncoated tablets, debossed with “GF1” and plain on other side.

- Ingredients

- Active ingredient(s)
Vildagliptin
- Inactive ingredients
Lactose anhydrous, microcrystalline cellulose, sodium starch glycolate, magnesium stearate

- MAL number
MAL23036023AZ

Manufacturer

Intas Pharmaceuticals Limited
Plot Numbers 457,458 & 191/218P,
Sarkhej-Bavla Highway, Matoda, Sanand,
Ahmedabad, Gujarat. IN-382210, India

Product Registration Holder

Lotus Healthcare Malaysia Sdn. Bhd.
UOA Business Park, Tower 3,
9th Floor, K03-09-11
1 Jalan Pengaturcara U1/51A
Section U1, 40150 Shah Alam
Selangor, Malaysia

Date of revision

05/05/2023

Serial Number

NPRA(R2) 22/107