

PACKAGE LEAFLET: Information for the patient

PROVILDA

Tablets – 50 mg

(Vildagliptin)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. What Provilda is and what it is used for
2. What you should know before you take Provilda
3. How to take Provilda
4. Possible side effects
5. How to store Provilda
6. Other information

1. WHAT PROVILDA IS AND WHAT IT IS USED FOR

The active substance of Provilda, vildagliptin, belongs to a group of medicines called “oral antidiabetics”.

Provilda is used to treat adult patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe Provilda either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not proved sufficiently effective to control diabetes. Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the 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 which helps to lower the level of sugar in the blood, especially after meals.

Glucagon is a substance which triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

How Provilda works

Provilda works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes. Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise which has been recommended for you.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE PROVILDA

Do not take Provilda:

- if you are allergic to vildagliptin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to vildagliptin or any of the other ingredients of Provilda, do not take this medicine and talk to your doctor.

Take special care with Provilda:

- if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis;
- if you are taking an anti-diabetic medicine known as a sulphonylurea (your doctor may want to reduce your dose of the sulphonylurea when you take it together with Provilda in order to avoid low blood glucose [hypoglycaemia]);
- if you have moderate or severe kidney disease (you will need to take a lower dose of Provilda);
- if you are on dialysis;
- if you have liver disease;
- if you suffer from heart failure;
- if you have or have had a disease of the pancreas.

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Provilda.

Should these occur, you should promptly consult your doctor.

A test to determine your liver function will be performed before the start of Provilda treatment, at three month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

Children and adolescents

The use of Provilda in children and adolescents up to 18 years of age is not recommended.

Other medicines and Provilda

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to alter your dose of Provilda if you are taking other medicines such as:

- thiazides or other diuretics (also called water tablets);
- corticosteroids (generally used to treat inflammation);
- thyroid medicines;
- certain medicines affecting the nervous system.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 use Provilda during pregnancy.

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

Driving and using machinery

If you feel dizzy while taking Provilda, do not drive or use machines.

Important information about some of the excipients of Provilda

Provilda tablets contain lactose. If you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE PROVILDA

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take and when

The amount of Provilda people have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of Provilda to take. The maximum daily dose is 100 mg.

The usual dose of Provilda is either:

- 50 mg daily taken as one dose in the morning if you are taking Provilda with another medicine called a sulphonylurea;
- 100 mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking Provilda alone, with another medicine called metformin or a glitazone, with a combination of metformin and a sulphonylurea, or with insulin;
- 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on dialysis.

How to take Provilda

- Swallow the tablets whole with some water.

How long to take Provilda

- Take Provilda every day for as long as your doctor tells you. You may have to take this treatment over a long period of time.
- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Provilda than you should

If you take too many Provilda tablets, or if someone else has taken your medicine, talk to your doctor straight away. Medical attention may be needed. If you need to see a doctor or go to the hospital, take the pack with you.

If you forget to take Provilda

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

If you stop taking Provilda

Do not stop taking Provilda unless your doctor tells you to. If you have questions about how long to take this medicine, talk to your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention:

You should stop taking Provilda and see your doctor immediately if you experience the following side effects:

- angioedema (rare: may affect up to 1 in 1,000 people): symptoms include swollen face, tongue or throat, difficulty swallowing, difficulties breathing, sudden onset rash or hives, which may indicate a reaction called “angioedema”
- liver disease (hepatitis) (rare): symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis)
- inflammation of the pancreas (pancreatitis) (frequency not known): symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects

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

- common (may affect up to 1 in 10 people): trembling, headache, dizziness, nausea, low blood glucose
- uncommon (may affect up to 1 in 100 people): tiredness.

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

- common: trembling, headache, dizziness, weakness, low blood glucose
- uncommon: constipation
- very rare (may affect up to 1 in 10,000 people): sore throat, runny nose.

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

- common: weight increase, swollen hands, ankle or feet (oedema)
- uncommon: headache, weakness, low blood glucose.

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

- common: dizziness
- uncommon: headache, constipation, swollen hands, ankle or feet (oedema), joint pain, low blood glucose
- very rare: sore throat, runny nose, fever.

Some patients have had the following side effects while taking vildagliptin, metformin and a sulphonylurea:

- common: dizziness, tremor, weakness, low blood glucose, excessive sweating.

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

- common: headache, chills, nausea (feeling sick), low blood glucose, heartburn
- uncommon: diarrhoea, flatulence.

Since vildagliptin has been marketed, the following side effects have also been reported:

- frequency not known (cannot be estimated from the available data): itchy rash, inflammation of the pancreas, localised peeling of skin or blisters, muscle pain.

If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE PROVILDA

Keep out of the reach and sight of children.

Do not use the tablets after the expiry date which is stated on the packaging.

Store in the original package in order to protect from moisture.

Do not store above 25°C!

6. OTHER INFORMATION

What Provilda tablets contain

The active substance is vildagliptin.

Each tablet contains 50 mg vildagliptin.

The excipients are: lactose anhydrous, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.

Contents of the pack

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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