Package leaflet: Information for the patient

ZADA PHARMACEUTICALS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor, pharmacist or nurse.This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Vildanorm Plus® 50 mg/850 mg film-coated tablets
Vildanorm Plus® 50 mg/1000 mg film-coated tablets
vildagliptin/metformin hydrochloride

What is in this leaflet

1. What **Vildanorm Plus** is and what it is used for?
2. What you need to know before you take **Vildanorm Plus**?
3. How to take **Vildanorm Plus**?
4. Possible side effects
5. How to store **Vildanorm Plus**?
6. Contents of the pack and other information

1. What Vildanorm Plus is and what it is used for?

The active substances of **Vildanorm Plus**, vildagliptin and metformin, belong to a group of medicines called "oral antidiabetics". **Vildanorm Plus** is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as noninsulin-dependent diabetes mellitus. 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.
Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals.
Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

How Vildanorm Plus works
Both active substances, vildagliptin and metformin, help to control the level of sugar in the blood. The substance vildagliptin works by making the pancreas produce more insulin and less glucagon. The substance metformin works by helping the body to make better use of insulin. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes.

2. What you need to know before you take Vildanorm Plus?

Do not take Vildanorm Plus
- if you are allergic to vildagliptin, metformin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to any of these, talk to your doctor before taking **Vildanorm Plus.**
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing which could be a sign of heart problems.
- if you have severely reduced kidney function.
- if you have a severe infection or are seriously dehydrated (have lost a lot of water from your body).
- if you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye).

Please also see information about this in section "Warnings and precautions".
- if you have liver problems.
- if you drink alcohol excessively (whether every day or only from time to time).
- if you are breast-feeding (see also "Pregnancy and breast-feeding").

Warnings and precautions
Risk of lactic acidosis
Vildanorm Plus may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions. Stop taking **Vildanorm Plus** for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking **Vildanorm Plus** and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:
- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital. **Vildanorm Plus** is not a substitute for insulin. Therefore, you should not receive **Vildanorm Plus** for the treatment of type 1 diabetes. Talk to your doctor, pharmacist or nurse before taking **Vildanorm Plus** if you have or have had a disease of the pancreas. Talk to your doctor, pharmacist or nurse before taking **Vildanorm Plus** 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 **Vildanorm Plus** in order to avoid low blood glucose (hypoglycaemia).
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 **Vildanorm Plus**. Should these occur, you should promptly consult your doctor.
If you need to have major surgery you must stop taking **Vildanorm Plus** during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with **Vildanorm Plus.**
A test to determine your liver function will be performed before the start of **Vildanorm Plus** 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.
During treatment with **Vildanorm Plus**, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function.
Your doctor will test your blood and urine for sugar regularly.

Children and adolescents
The use of **Vildanorm Plus** in children and adolescents up to 18 years of age is not recommended.

Other medicines and Vildanorm Plus
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking **Vildanorm Plus** before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with **Vildanorm Plus.**
Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of **Vildanorm Plus.** It is especially important to mention the following:
- glucocorticoids generally used to treat inflammation
- beta-2 agonists generally used to treat respiratory disorders
- other medicines used to treat diabetes
- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- certain medicines affecting the thyroid, or
- certain medicines affecting the nervous system.

Vildanorm Plus with alcohol
Avoid excessive alcohol intake while taking **Vildanorm Plus** since this may increase the risk of lactic acidosis (please see section "Warnings and precautions").

Pregnancy and breast-feeding
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risk of taking **Vildanorm Plus** during pregnancy.
- Do not use **Vildanorm Plus** if you are pregnant or breast-feeding (see also "Do not take Vildanorm Plus").

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

Driving and using machines
If you feel dizzy while taking **Vildanorm Plus**, do not drive or use any tools or machines.

3. How to take Vildanorm Plus?
The amount of **Vildanorm Plus** that people have to take varies depending on their condition. Your doctor will tell you exactly the dose of **Vildanorm Plus** to take.
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is one film-coated tablet of either 50 mg/850 mg or 50 mg/1000 mg taken twice a day. If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.
Your doctor may prescribe this medicine alone or with certain other medicines that lower the level of sugar in your blood.

When and how to take **Vildanorm Plus**?
- Swallow the tablets whole with a glass of water,
- Take one tablet in the morning and the other in the evening with or just after food. Taking the tablet just after food will lower the risk of an upset stomach.

Continue to follow any advice about diet that your doctor has given you. In particular, if you are following a diabetic weight control diet, continue with this while you are taking **Vildanorm Plus**.

If you take more Vildanorm Plus than you should
If you take too many **Vildanorm Plus** tablets, or if someone else takes your tablets, talk to a doctor or pharmacist immediately. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take Vildanorm Plus
If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Vildanorm Plus
Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking **Vildanorm Plus** unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. You should stop taking **Vildanorm Plus** and see your doctor immediately if you experience the following side effects:
- Lactic acidosis (very rare: may affect up to 1 user in 10,000): **Vildanorm Plus** may cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens you must stop taking **Vildanorm Plus** and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.
- Angioedema (rare: may affect up to 1 in 1,000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of 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 experienced the following side effects while taking **Vildanorm Plus**:
- **Very common** (may affect more than 1 in 10 people): nausea, vomiting, diarrhoea, pain in and around the stomach (abdominal pain), loss of appetite.
- **Common** (may affect up to 1 in 10 people): dizziness, headache, trembling that cannot be controlled, metallic taste, low blood glucose.
- **Uncommon** (may affect up to 1 in 100 people): joint pain, tiredness, constipation, swollen hands, ankle or feet (oedema).
- **Very rare** (may affect up to 1 in 10,000 people): sore throat, runny nose, fever; signs of a high level of lactic acid in the blood (known as lactic acidosis) such as drowsiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heart beat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances).

Some patients have experienced the following side effects while taking **Vildanorm Plus** and a sulphonylurea:
- **Common**: dizziness, tremor, weakness, low blood glucose, excessive sweating.

Some patients have had the following side effects while taking **Vildanorm Plus** and insulin:
- **Common**: headache, chills, nausea (feeling sick), low blood glucose, heartburn.
- **Uncommon**: diarrhoea, flatulence.

Since this product 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vildanorm Plus?
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package (blister) in order to protect from moisture.

6. Contents of the pack and other information
What **Vildanorm Plus** contains?
The active substances are vildagliptin and metformin hydrochloride.
- Each **Vildanorm Plus** 50 mg/850 mg film-coated tablet contains 50 mg vildagliptin and 850 mg metformin hydrochloride.
- Each **Vildanorm Plus** 50 mg/1000 mg film-coated tablet contains 50 mg vildagliptin and 1000 mg metformin hydrochloride.

Other ingredients: microcristalline cellulose, PVPK-30, iso propyl alcohol, croscarmellose sodium, aerosil colloidel silicon, magnesium stearate, hydroxypropylmethylcellulose, polyethylene glycol, colour titanium dioxide, ferric oxide (yellow), purified talcum, dichloromethane.

What Vildanorm Plus looks like and contents of the pack?
Vildanorm Plus 50 mg/850 mg film-coated tablet
Cardboard box with 60 (6x10) 50 mg/850 mg film-coated tablet vildagliptin/metformin hydrochloride film-coated tablets, in blister packs.
Cardboard box with 30 (3x10) 50 mg/850 mg film-coated tablet vildagliptin/metformin hydrochloride film-coated tablets, in blister packs.

Vildanorm Plus 50 mg/1000 mg film-coated tablet
Cardboard box with 60 (6x10) 50 mg/1000 mg film-coated tablet vildagliptin/metformin hydrochloride film-coated tablets, in blister packs.
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Marketing Authorisation Holder and Manufacturer
ZADA Pharmaceuticals Ltd.
Donji Bistarac bb
75300 Lukavac
Bosnia and Herzegovina

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