Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
The medicine is dispensed with a doctor's prescription only

Viformin 50/850 mg Viformin 50/1000 mg

Film-Coated Tablets **Film-Coated Tablets**

Active ingredients

Viformin 50 mg/850 mg:
vildagliptin 50 mg and metformin hydrochloride 850 mg

Viformin 50 mg/1000 mg:
vildagliptin 50 mg and metformin hydrochloride 1000 mg

Inactive ingredients in this medicine: See section 6 'Additional information'.
Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Viformin is intended for treatment of type 2 diabetes. Viformin is intended for treatment in adults already receiving combined treatment with separate tablets of vildagliptin and metformin hydrochloride, or whose diabetes is not controlled with metformin hydrochloride alone.
Your doctor will prescribe treatment with Viformin either alone or in combination with another diabetes medicine depending on your condition. Viformin is also indicated in combination with insulin or a medicine from the sulfonylurea group as an adjunct to diet and exercise in adult patients.

Therapeutic group:
vildagliptin - dipeptidyl-peptidase-4 (DPP-4) inhibitor.
metformin - biguanides.

Both active ingredients are oral antidiabetic medicines.
Type 2 diabetes develops when the body does not produce enough insulin, or when the insulin that the body produces does not work properly or when the body produces too much glucagon.
Insulin is a substance which helps to lower the level of glucose in the blood, especially after meals. Glucagon is a substance that stimulates the liver to produce glucose, causing the blood glucose level to rise. Both of these substances are produced in the pancreas. Both active substances in the medicine Viformin help to control the level of glucose in the blood.
Viformin makes the pancreas produce more insulin and less glucagon (effect of vildagliptin), and also helps the body to make better use of the secreted insulin (effect of metformin hydrochloride).

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to vildagliptin, metformin hydrochloride or to any of the other ingredients in this medicine (see section 6 'Additional information'). If you think you may be allergic to any of these ingredients, talk to your doctor before taking Viformin.
- Your diabetes is uncontrolled with, for example, severe hyperglycemia (high blood glucose level), nausea, vomiting, diarrhea, 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 can lead to diabetic pre-coma. The symptoms include abdominal pain, fast and deep breathing, sleepiness or breath with an unusual fruity smell.
- You have recently had a heart attack or if you have heart failure or serious problems with the blood circulation or difficulties in breathing, which could be a sign of heart problems.
- You have severely reduced kidney function.
- You have a severe infection or are seriously dehydrated (have lost a lot of water from your body).
- You are going to have an x-ray (a specific type of x-ray including injection of an iodine-containing contrast agent) (see section 'Drug interactions').
- You have liver function problems.
- You drink alcohol excessively (whether every day or only from time to time).
- You are breastfeeding (see also 'Pregnancy, breastfeeding and fertility').

Special warnings about using this medicine

Risk of lactic acidosis

Viformin 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 consumption, dehydration (see further information below), liver function 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 conditions apply to you, talk to your doctor to receive further instructions.

Stop taking Viformin for a short time if you have a condition that is associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhea, fever, exposure to heat or if you are drinking less fluids than usual. Talk to your doctor for further instructions.

Stop taking Viformin and contact a doctor or go to the nearest hospital immediately if you experience any of the symptoms of lactic acidosis, as this condition may lead to coma.
Symptoms of lactic acidosis include:

- vomiting
- abdominal pain
- muscle cramps
- a general feeling of being unwell with severe fatigue
- difficulty breathing
- reduced body temperature and lower heart rate

Lactic acidosis is a medical emergency and must be treated in a hospital.

Refer to a doctor immediately for additional instructions if:

- you are known to suffer from a genetically inherited disease that affects the mitochondria (energy-producing components within cells) such as MELAS syndrome (mitochondrial encephalopathy, myopathy, lactic acidosis and stroke-like episodes) or maternal-inherited diabetes and deafness (MIDD).
- You experience any of the following symptoms after starting treatment within metformin: seizures, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g., pain or numbness), migraine and deafness.

Viformin is not a substitute for insulin. Therefore, you should not take Viformin for the treatment of type 1 diabetes.

Before using Viformin, tell your doctor if:

- You have or have had a disease of the pancreas.
- You are taking a medicine from the sulfonylurea group to treat diabetes. Your doctor may want to lower your dose of the medicine from the sulfonylurea group when it is given together with Viformin in order to prevent a low blood glucose level (hypoglycemia).
- You have previously taken vildagliptin but had to stop because of liver disease; do not take this medicine.
- You have decreased kidney function. Your doctor may prescribe you a lower dose of Viformin, depending on your kidney function.

During treatment with Viformin:

- 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 the development of new blisters or ulcers while taking Viformin. If these occur, you should immediately consult your doctor.
- If you are about to undergo surgery, stop taking Viformin before and for some time after surgery. Your doctor will decide when you must stop and when to restart your treatment with Viformin.

Children and adolescents

Use of Viformin is not intended for children and adolescents under 18 years of age.

Tests and follow-up

- Before starting treatment with Viformin, your doctor will refer you for a liver function test. During the first year of treatment with the medicine, a test should be performed every three months, and afterwards tests should be performed periodically so that an increase in liver enzymes can be diagnosed at an early stage.
- During treatment, your doctor will monitor the levels of glucose in your blood and urine from time to time.
- Before you start and during treatment with Viformin, your doctor will check your kidney function at least once a year, and at a higher frequency if you are elderly and/or there is worsening of your kidney function.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

If you need to have an injection of an iodine-containing contrast agent into your bloodstream, for example during an X-ray or scan, you must stop taking Viformin before the injection. Your doctor will decide when you must stop and when you should restart your treatment with Viformin.

If you are taking other medicines, your doctor may refer you for more frequent testing of your blood glucose levels and kidney function, or you doctor may need to adjust the dose of Viformin accordingly.
It is especially important to mention medicines you are taking from the following groups:

- glucocorticoids generally used to treat inflammation
- beta-2 agonists usually used to treat respiratory disorders
- other medicines used to treat diabetes
- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (non-steroidal anti-inflammatory drugs [NSAIDs] and COX-2 inhibitors such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (angiotensin-converting enzyme [ACE] inhibitors and angiotensin II receptor antagonists)
- certain medicines affecting the thyroid
- certain medicines affecting the nervous system
- certain medicines used to treat angina (such as ranolazine)
- certain medicines used to treat HIV infection (such as dolutegravir)
- certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (such as vandetanib)
- certain medicines used to treat heartburn and peptic ulcers (such as cimetidine)

Using Viformin and food
It is advisable to take the tablets either with or just after a meal. This will reduce the risk of getting an upset stomach.

Using Viformin and alcohol consumption
Refrain from excessive consumption of alcohol during treatment with Viformin, since alcohol consumption may increase the risk of lactic acidosis (see section 'Special warnings about using this medicine').

Pregnancy, breastfeeding, and fertility
Pregnancy
Tell your doctor if you are pregnant, think you are pregnant, or are planning to become pregnant. Your doctor will discuss the potential risk of taking Viformin during pregnancy with you. There is insufficient information about using Viformin during pregnancy, and therefore you should not use Viformin if you are pregnant.
Breastfeeding
Do not use Viformin if you are breastfeeding (also see 'Do not use this medicine if:').
Fertility
There is no information from clinical studies.

Driving and using machines
If you feel dizzy while taking Viformin, refrain from driving vehicles or using tools or machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.
The recommended dosage is usually one tablet, twice daily. If you have abnormal kidney function or you are taking a medicine from the sulfonylurea group, your doctor may prescribe you a lower dose of Viformin.
The medicine may be prescribed for you alone or as part of combination therapy along with other medicines that lower the level of glucose in your blood.

Do not exceed the recommended dose.
If you have questions about how long to take Viformin, contact your doctor.

Do not chew! The tablets are film-coated. Swallow the tablets whole with a glass of water.
It is advisable to take the tablets either with or just after a meal. This will reduce the chance of getting an upset stomach.
Take one tablet in the morning and one tablet in the evening.
During treatment, continue to follow any instructions about diet that your doctor has given you, particularly if you are following a diet designed for diabetes patients.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Medical treatment might be necessary.

If you forget to take the medicine at the scheduled time, take a dose with your next meal. If you are due to take a dose at the next meal anyway, skip the forgotten dose. Never take a double dose (two tablets at once) to make up for a missed dose.

Adhere to the treatment as recommended by your doctor, so that the medicine can continue to control your blood glucose.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

As with any medicine, using Viformin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking Viformin and consult your doctor immediately if you experience one or more of the following symptoms:

- **Lactic acidosis** (very rare: affects less than 1 in 10,000 users):
  Viformin may cause a very rare but very serious side effect called lactic acidosis (see section 'Special warnings about using this medicine'). If this happens, **stop taking Viformin and contact a doctor or go to the nearest hospital immediately,** as lactic acidosis may lead to coma.
- Angioedema (rare: affects 1-10 in 10,000 users):
  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) (uncommon: affects 1-10 in 1,000 users):
  Symptoms include yellow skin and eyes, nausea, loss of appetite, dark-colored urine, which may indicate liver disease (hepatitis).

- Inflammation of the pancreas (pancreatitis) (uncommon: affects 1-10 in 1,000 users):
  Symptoms include severe and persistent pain in the abdominal area, which may radiate to your back as well as nausea and vomiting.

Other side effects:
Some patients have experienced the following side effects while taking Viformin:

- Common side effects (affect 1-10 in 100 users):
  sore throat, runny nose, fever, itchy rash, excessive sweating, joint pain, dizziness, headache, uncontrollable tremor, constipation, nausea, vomiting, diarrhea, flatulence, heartburn, pain in and around the stomach (abdominal pain).
- Uncommon side effects (affect 1-10 in 1,000 users):
  tiredness, weakness, metallic taste, low blood glucose level, loss of appetite, swollen hands, ankles or feet (edema), chills, pancreatitis, muscle pain.
- Very rare side effects (affect less than 1 in 10,000 users):
  signs of a high level of lactic acid in the blood (a condition called lactic acidosis) such as sleepiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heartbeat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, signs such as confusion or memory disturbances).

Since this medicine has been marketed, the following side effects have been reported:
Frequency unknown (cannot be estimated from the available data): localized peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects
You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use this medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store below 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:
Core tablet: microcrystalline cellulose, copovidone, crospovidone, hydroxypropylcellulose, magnesium stearate.
Film-coating: HPMC 2910, titanium dioxide, iron oxide yellow, macrogol, talc.

What the medicine looks like and contents of the pack:

Viformin 50 mg/850 mg: yellow, oval, film-coated tablets, with beveled edges.

Viformin 50 mg/1000 mg: dark yellow, oval, film-coated tablets, with beveled edges.

Pack sizes: 28, 30, 56, 60 tablets.
Not all pack sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761.

Manufacturer's name and address:
Bluepharma Industria Farmaceut.S.A., Sao Martino Do Bispo,3045-16 Coimbra, Portugal

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Registration numbers of the medicine in the Ministry of Health's National Drug Registry:
Viformin 50 mg/850 mg: 175-56-36845-99
Viformin 50 mg/1000 mg: 175-57-36846-99

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:

https://israeldrugs.health.gov.il/#!/medDetails/175%2056%2036845%2099

For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.