

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Linagliptin Inovamed

5 mg film-coated tablets

Active ingredient:

Each film-coated tablet of Linagliptin Inovamed contains: Linagliptin 5 mg.

Inactive ingredients and allergens in the preparation – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist. This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

Linagliptin Inovamed is intended to improve control of blood sugar levels in adults with type 2 diabetes, in addition to diet and exercise.

Limitations of use: do not use Linagliptin Inovamed to treat type 1 diabetes or to treat diabetic ketoacidosis, because Linagliptin Inovamed is not effective in these conditions.

Linagliptin Inovamed has not been studied in patients who have previously had inflammation of the pancreas (pancreatitis). It is not known whether patients who have previously suffered from pancreatitis are at an increased risk of developing pancreatitis during treatment with Linagliptin Inovamed.

Linagliptin Inovamed can be given as monotherapy or in combination with additional medicinal products to reduce blood sugar levels.

Therapeutic class: inhibitors of the DPP-4 (dipeptidyl peptidase-4) enzyme

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient linagliptin or to any of the other ingredients the medicine contains (for a list of inactive ingredients, see section 6 "Additional information". In addition see in section 2 "Important information about some of the ingredients of the medicine"). Symptoms of a severe allergic reaction to Linagliptin Inovamed may include:
 - Skin rash, itching, flaking or peeling
 - Raised red patches on your skin (hives)
 - Swelling of your face, lips, tongue and throat that may cause difficulty in breathing or swallowing
 - Difficulty swallowing or breathingIf you experience any of these symptoms, stop taking Linagliptin Inovamed and refer to your doctor **immediately** or go to the nearest hospital emergency room.

Special warnings regarding the use of the medicine

Before treatment with Linagliptin Inovamed, inform the doctor about your medical condition, including if:

- You are taking additional medicines to lower blood sugar, especially medicines called "sulfonylurea" (such as gliimepiride) or insulin. Combining these medicines with Linagliptin Inovamed increases the risk of a drop in blood sugar (hypoglycemia). The doctor may want to reduce the dosage of the sulfonylurea or insulin. See details in section 4 "Side effects".
- You have or have had in the past inflammation of the pancreas (pancreatitis), gallstones, alcoholism, high blood triglyceride levels.
- You have previously had angioedema (localized edema due to excessive infiltration of fluid out of blood vessels) due to taking another medicine from the DPP-4 enzyme inhibitor group.
- You have ever had heart failure or you have problems with your kidneys.
- You are pregnant or planning to become pregnant. See section 2 "Pregnancy, breastfeeding and fertility".
- You are breastfeeding or planning to breastfeed. See section 2 "Pregnancy, breastfeeding and fertility".

After taking Linagliptin Inovamed, tell the doctor immediately:

- Pancreatitis** (see section 4 – "Side effects") can occur in patients treated with Linagliptin Inovamed; it may be severe and lead to death. Certain medical problems may increase the risk of pancreatitis.

Stop taking Linagliptin Inovamed and consult the doctor immediately if you have abdominal pain (in the stomach area) that is severe and does not go away. The pain may radiate from the abdomen to the back, and the pain can appear with or without vomiting. These may be symptoms of pancreatitis.

- If you have any of the following symptoms:
 - Increasing shortness of breath or trouble breathing, especially when you lie down
 - Swelling or fluid retention, especially in the feet, ankles or legs
 - An unusually fast increase in weight
 - Unusual tiredness

All these may be symptoms of heart failure. Heart failure means that your heart does not pump blood well enough.

- Serious allergic reactions have happened in people taking Linagliptin Inovamed. The symptoms may include:
 - Swelling of the face, lips, tongue, throat and other areas on your skin.
 - Raised red areas on your skin (hives).
 - Difficulty swallowing or breathing.
 - Skin rash, itching, flaking or peeling.

If you experience any of these symptoms, stop taking Linagliptin Inovamed and refer **immediately** to your doctor or go to the nearest hospital emergency room.

- Some patients who take Linagliptin Inovamed may develop joint pain which may be severe and disabling. Consult the doctor **immediately** if you have severe joint pain.

- Some patients who take medicines called DPP-4 inhibitors, such as Linagliptin Inovamed, may develop a skin reaction called bullous pemphigoid, which may require treatment in a hospital. Refer to your doctor **immediately** if you develop blisters or sores on the upper layer of the skin (erosions). Your doctor may instruct you to stop the treatment with Linagliptin Inovamed.

Children and adolescents

It is unknown whether Linagliptin Inovamed is safe and effective in children and adolescents under the age of 18.

Tests and follow-up

- During the treatment period, blood sugar levels should be checked according to the doctor's instructions.
- Consult the doctor on how to prevent, identify and treat low blood sugar levels (hypoglycemia), high blood sugar levels (hyperglycemia) and diabetes complications.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Linagliptin Inovamed may affect the way other medicines work, and other medicines may affect the way Linagliptin Inovamed works. In particular, tell your doctor if you are taking:

- Insulin or other medicines that can lower your blood sugar. Your doctor may instruct you to take Linagliptin Inovamed together with other diabetes medicines. Low blood sugar may happen more frequently when Linagliptin Inovamed is taken together with certain other diabetes medicines. See section 2 "Before treatment with Linagliptin Inovamed, inform the doctor about your medical condition, including if" and section 4 "Side effects".
- Rifampicin, an antibiotic used to treat tuberculosis.

Get to know the medicines you are taking. Keep a list of them to show the doctor and pharmacist when you get a new medicine.

Use of the medicine and food

This medicine may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant, planning a pregnancy, breastfeeding or planning to breastfeed, consult the doctor before use.

- It is not known whether Linagliptin Inovamed will harm the unborn baby. If you are pregnant, talk to your doctor regarding the best way to control your blood sugar levels during pregnancy.
- It is not known whether Linagliptin Inovamed passes into your breast milk. Consult your doctor regarding the best way to feed your baby if you are taking Linagliptin Inovamed.

Important information about some of the ingredients of the medicine

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, and is thus considered to be "sodium-free".

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined by the doctor only.

The generally accepted dosage is one film-coated tablet once a day.

In patient populations with kidney or liver insufficiency there is no need to adjust the dosage of the medicine.

Do not exceed the recommended dose.

Swallow the medicine with water. No information is available regarding crushing/halving/chewing.

If you accidentally took a higher dosage: if you took an overdose or if a child accidentally swallowed the medicine, refer **immediately** to the doctor or to the nearest hospital emergency room and take the package of the medicine with you.

If you forgot to take the medicine at the required time, take it as soon as you remember. If you do not remember until it is time to take the next dose, skip the missed dose and return to the regular schedule. Do not take two doses of Linagliptin Inovamed together. Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. **If you stop taking the medicine**, your blood sugar levels may increase.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Linagliptin Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The side effects listed below occurred when Linagliptin Inovamed was used on its own or when Linagliptin Inovamed was taken in combination with other preparations for controlling diabetes.

Linagliptin Inovamed may cause serious side effects, including:

- Inflammation of the pancreas (pancreatitis) [an uncommon side effect – effect that occurs in 1-10 users out of 1000]** which may be severe and lead to death. Certain medical problems increase the likelihood of pancreatitis.

Before you start taking Linagliptin Inovamed, tell your doctor if you have ever had:

- Inflammation of your pancreas (pancreatitis)
- A history of alcoholism
- Stones in your gallbladder
- High blood triglyceride levels

Stop taking Linagliptin Inovamed and consult the doctor immediately if you have abdominal pain (in the stomach area) that is severe and does not go away. The pain may radiate from the abdomen to the back. The pain may appear with or without vomiting. These may be symptoms of pancreatitis.

- Low blood sugar levels (hypoglycemia) [a very common side effect – effect that occurs in more than one user out of 10].** If you are taking Linagliptin Inovamed with another medicine that may cause low blood sugar, such as sulfonylurea or insulin, your risk of low blood sugar levels is higher. It may be necessary to lower the dosage of the sulfonylurea medicine or insulin while you are taking Linagliptin Inovamed. Signs and symptoms of low blood sugar may include:
 - Headache
 - Irritability
 - Drowsiness
 - Hunger
 - Weakness
 - Fast heartbeat
 - Dizziness
 - Sweating
 - Confusion
 - Shaking or feeling jittery

- Allergic reactions (hypersensitivity) (unknown frequency).** Severe allergic reactions have appeared in people taking Linagliptin Inovamed. The symptoms may include:
 - Swelling of the face, lips, tongue, throat and other areas on your skin.
 - Raised red areas on your skin (hives).
 - Difficulty swallowing or breathing.
 - Skin rash, itching, flaking or peeling.

If you experience any of these symptoms, stop taking Linagliptin Inovamed and refer **immediately** to your doctor or go to the nearest hospital emergency room.

- Severe, disabling joint pain (unknown frequency).** Some patients who take Linagliptin Inovamed may develop joint pain which may be severe and disabling. Consult the doctor **immediately** if you have severe joint pain.
- Skin reaction (unknown frequency).** Some patients who take medicines called DPP-4 inhibitors, such as Linagliptin Inovamed, may develop a skin reaction called bullous pemphigoid, which may require treatment in a hospital. Refer to your doctor **immediately** if you develop blisters or sores on the upper layer of the skin (erosion). Your doctor may instruct you to stop the treatment with Linagliptin Inovamed.

- Heart failure.** Heart failure means that your heart does not pump blood well enough.

Before you start taking Linagliptin Inovamed, tell your doctor if you have ever had heart failure or problems with your kidneys. Refer to your doctor **immediately** if you have any of the following symptoms:

- Increasing shortness of breath or trouble breathing, especially when you lie down
- Swelling or fluid retention, especially in the feet, ankles or legs
- An unusually fast increase in weight
- Unusual tiredness

These may be symptoms of heart failure.

Common side effects, effects that occur in 1-10 users out of 100:

- Stuffy nose or runny nose and sore throat
- Diarrhea
- Cough
- Urinary tract inflammation
- High blood levels of fats (lipids or triglycerides)
- Weight gain
- Constipation
- Back pain
- Joint pain
- Upper respiratory tract infection
- Headache
- Pain in the extremities
- In a laboratory test: an increase in uric acid, an increase of enzymes that break up fat (lipase), an increase in the enzyme amylase

Additional side effects with unknown frequency (effects whose frequency has not yet been determined):

- Muscle pain
- Mouth ulcers, inflammation of the oral cavity (stomatitis)
- Breakdown of muscle (rhabdomyolysis)
- Rash

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Mannitol; cellulose, microcrystalline; copovidone (K-28); sodium starch glycolate, type A; hypromellose, type 2910; sodium stearyl fumarate; titanium dioxide; talc; macrogol, MW 6000; iron oxide red (E172).

What does the medicine look like and what are the contents of the package?

Linagliptin Inovamed is a round, biconvex, pink film-coated tablet, debossed with "5" on one side.

Package type:

The medicine is supplied in a carton package containing trays (blisters) with a total of 30 film-coated tablets.

Manufacturer: Zakłady Farmaceutyczne Polpharma S.A., Poland. License holder and importer: Inovamed Pharma Ltd., P.O. Box 2349, Bnei Brak.

Revised in August 2025.

Registration number of the medicine in the national drug registry of the Ministry of Health:

176-06-36952