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| Trajenta | Updated patient information |
| Film-coated tablets 5 mg | September 2022 |

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

# Trajenta®
## 5 mg film-coated tablets

Each film-coated tablet of **Trajenta** contains: 5 mg linagliptin.

Inactive ingredients and allergens in this preparation - see section 6 'Additional information'.

**Read the entire leaflet carefully before you start using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, contact the 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?

In addition to diet and physical activity, Trajenta is intended to improve control of blood sugar levels in adults with type 2 diabetes. Trajenta can be given as monotherapy or in combination with additional medicinal products to reduce blood sugar levels.

**Limitations of use:** Do not use Trajenta to treat type 1 diabetes or diabetic ketoacidosis, because Trajenta is not effective with these conditions.
Trajenta 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 the treatment with Trajenta.

**Therapeutic group:** inhibitors of the enzyme DPP-4 (dipeptidyl peptidase-4).

## 2. Before using this medicine

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient linagliptin or to any of the additional ingredients in the medicine (for a list of inactive ingredients, please see section 6 'Additional information'). Symptoms of severe allergic reaction to Trajenta may include skin rash, itching, flaking or peeling of the skin, raised red patches on your skin (hives), swelling of your face, lips, tongue and throat which may cause difficulty breathing or swallowing, difficulty swallowing or breathing.
  If you experience any of these symptoms, stop taking Trajenta and call your doctor immediately or go to the emergency room in the nearest hospital.

**Special warnings about using this medicine**
**Before using Trajenta, tell the doctor about your medical condition, including if:**

- You are taking additional medicines to lower your blood sugar, especially medicines called "sulfonylurea" (such as glimepiride) or insulin. Combining these medicines with Trajenta increases the risk of getting low blood sugar level (hypoglycemia). The doctor may want to reduce the dose of sulfonylurea or insulin. See details in section 4, 'Side effects'.
- You have or have had inflammation of your pancreas (pancreatitis), gallstones, alcoholism, high levels of triglycerides in the blood.
- You have had angioedema (localized edema due to excessive infiltration of fluid from the blood vessels) because you are taking another medicine from the DPP-4 inhibitor group.
- You have ever had heart failure or problems with your kidneys.

- You are pregnant or plan to become pregnant. See section 2, 'Pregnancy, breastfeeding, and fertility'.
- You are breastfeeding or plan to breastfeed. See section 2, 'Pregnancy, breastfeeding, and fertility'.

**After taking Trajenta, tell the doctor immediately:**

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

**Stop taking Trajenta and consult the doctor immediately if** there is a pain in the stomach area (abdomen) that is severe and will 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 your heart does not pump blood well enough.

- Serious allergic reactions have happened in people who are taking Trajenta. 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 with swallowing or breathing.
  - skin rash, itching, flaking, or peeling.

  If you have any of these symptoms, stop taking Trajenta and contact your doctor **immediately** or go to the emergency room in the nearest hospital.

- Some patients who take medicines called DPP-4 inhibitors, like Trajenta, may develop joint pain that may be severe and disabling. Consult the doctor right away if you have severe joint pain.

- Some patients who take medicines called DPP-4 inhibitors, like Trajenta, may develop a skin reaction called bullous pemphigoid that may require treatment in a hospital. Contact your doctor right away if you develop blisters or sores on the outer layer of the skin (erosions). Your doctor may tell you to stop taking Trajenta.

**Children and adolescents**

The safety and efficacy of the medicine have not been tested in children and adolescents under 18 years old.

**Tests and follow-up**

- During the course of treatment, the blood sugar levels must be tested 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 nonprescription medications and dietary supplements, tell the doctor or pharmacist.** Trajenta may affect the way other medicines work, and other medicines may affect the way Trajenta works. Particularly tell the doctor if you are taking:

- insulin or other medicines that can lower your blood sugar.
  Your doctor may tell you to take Trajenta along with other diabetes medicines. Low blood sugar may happen more often when Trajenta is taken with other diabetes medicines. See under

'Before using Trajenta, tell the doctor about your medical condition, including if:' and section 4, 'Side effects'.

- rifampicin, an antibiotic that is used to treat tuberculosis.

Know the medicines you take. Keep a list of them to show the doctor and pharmacist when you get a new medicine.

**Using the medicine and food**
The medicine can be taken with or without food.

**Pregnancy, breastfeeding, and fertility**
If you are pregnant, plan to become pregnant, are breastfeeding or plan to breastfeed, consult a doctor before taking the medicine.

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

## 3. How to use this medicine?

Always use this preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dose and about how to take the medicine.
Only your doctor will determine the dose and how you should take the medicine.
The recommended dose is usually one film-coated tablet, once a day.
**Patients with kidney failure or liver failure** do not require a dose adjustment.

**Do not exceed the recommended dose**.

Swallow the medicine with water. There is no information about crushing/splitting/chewing.

**If you have accidentally taken a higher dose:** If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately contact a doctor or go to a hospital emergency room and bring the medicine package with you.

**If you forget to take the medicine** at the scheduled time, take it as soon as you remember. If you do not remember until it is time to take the next dose, skip the forgotten dose and go back to the regular schedule. Do not take two doses of Trajenta together.

Adhere to the treatment as recommended by the doctor.
Even if your health improves, do not stop taking the medicine without consulting the doctor. **If you stop taking this medicine** your blood sugar levels may go up.

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

**If you have further questions about using the medicine, consult the doctor or pharmacist.**

## 4. Side effects

Like with all medicines, using Trajenta may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

**Trajenta may cause serious side effects including:**

- **Inflammation of the pancreas (pancreatitis) (uncommon side effect - effect that occurs in 1-10 users in 1,000)** which may be severe and lead to death. Certain medical problems increase the likelihood of pancreatitis.

**Before you start taking Trajenta**, 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 Trajenta and consult the doctor immediately if** there is a pain in the stomach area (abdomen) that is severe and will not go away. The pain may radiate from the abdomen to the back. The pain can appear with or without vomiting. These may be symptoms of pancreatitis.

- **Low blood sugar levels (hypoglycemia) (very common side effect - effect that occurs in more than 1 user in 10).** If you are taking Trajenta with another medicine that may cause low blood sugar, such as sulfonylurea or insulin, your risk of getting low blood sugar levels is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take Trajenta. 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 happened in people taking Trajenta. 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 Trajenta and contact your doctor **immediately** or go to the emergency room in the nearest hospital.

- **Severe, disabling joint pain (unknown frequency).** Certain patients who take medicines called DPP-4 inhibitors, such as Trajenta, may develop joint pain which may be severe and disabling. Consult the doctor immediately if you have sever joint pain.

- **Skin reaction (unknown frequency).** Certain patients who take medicines called DPP-4 inhibitors, such as Trajenta, may develop a skin reaction called bullous pemphigoid, which may require treatment in hospital. Contact your doctor **immediately** if you develop blisters or sores on the upper layer of the skin (erosions). Your doctor may tell you to stop taking Trajenta.

- **Heart failure (unknown frequency).** Heart failure means that your heart does not pump blood well enough**.**
  **Before you start taking Trajenta**, tell your doctor if you have ever had heart failure or problems with your kidneys. Contact 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 could be symptoms of heart failure.

**Common side effects, effects that occur in 1-10 users in 100:**
- stuffy or runny nose and sore throat
- diarrhea
- cough
- urinary tract infection
- 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 laboratory test: increase in uric acid, increase of enzymes that break up fats (lipase), increase in the enzyme amylase.

**Other side effects of unknown frequency (side effects whose frequency has not been established yet):**
- muscle pain
- mouth ulcers, inflammation of the mouth (stomatitis)
- breakdown of muscle (rhabdomyolysis)
- rash.

The side effects listed above occurred when Trajenta was used on its own or together with other medicines used to control diabetes.

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

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. 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 a doctor.
Do not use the 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.

## 6. Additional information

In addition to the active ingredient the medicine also contains the following inactive ingredients: mannitol, pregelatinized starch, maize starch, copovidone, magnesium stearate, hypromellose, titanium dioxide, talc, macrogol, red iron oxide.

What the medicine looks like and what are the contents of the pack:
Trajenta is a film-coated, light red, round, bi-convex, beveled edged tablet. The logo of Boehringer Ingelheim is debossed on one side and D5 is debossed on the other.
Packs contain blisters of film coated tablets . Each pack contains 7, 30, or 90 film-coated tablets.
Not all pack sizes may be marketed.

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Registration holder and importer's name and address: Boehringer Ingelheim Israel Ltd., 89 Medinat HaYehudim St., P.O.B. 4124, Herzeliya Pituach 4676672.

**This leaflet was revised in September 2022 according to MOH guidelines.**

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 149-96-33738-00.