

## PART III: CONSUMER INFORMATION

PrTrajenta®  
Linagliptin Tablets

This leaflet is part III of a three-part "Product Monograph" published when TRAJENTA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TRAJENTA. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

#### What the medication is used for:

TRAJENTA, along with diet and exercise to improve control of blood sugar in adults with type 2 diabetes, is used:

- alone in patients who cannot take metformin, or
- in combination with metformin, or
- in combination with a sulfonylurea, or
- in combination with metformin and a sulfonylurea, or
- in combination with metformin and empagliflozin, or
- in combination with insulin (with or without metformin).

#### What it does:

TRAJENTA is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). TRAJENTA helps to improve the levels of insulin when blood sugar level is high, especially after a meal. TRAJENTA also helps to decrease the amount of sugar made by the body.

#### When it should not be used:

You should not take TRAJENTA if:

- you are allergic (hypersensitive) to linagliptin or any of the non-medicinal ingredients listed below.
- you have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting).

#### What the medicinal ingredient is:

linagliptin

#### What the important non-medicinal ingredients are:

TRAJENTA tablets contain the following non-medicinal ingredients: mannitol, pregelatinised starch, maize starch, copovidone, magnesium stearate. In addition, the film coating contains the following inactive ingredients: hypromellose, titanium dioxide, talc, macrogol, iron oxide red.

#### What dosage forms it comes in:

TRAJENTA is supplied as tablets containing 5 mg linagliptin. The tablets are round, light red in colour and have the marking "D5" on one side.

### WARNINGS AND PRECAUTIONS

#### **BEFORE you use TRAJENTA talk to your doctor or pharmacist if:**

- you take sulfonylurea or insulin. Your doctor may reduce your dose of these products when you take them with TRAJENTA. This can help avoid low blood sugar. Your physician may consider lowering the dose of the sulfonylurea or insulin.
- you have had allergic reactions to any other medicines that you take to control the amount of sugar in your blood;
- you are pregnant or planning to become pregnant;
- you are breast-feeding or plan to breast-feed;
- you have or have had pancreas problems such as inflammation of the pancreas (pancreatitis);
- you have risk factors for pancreatitis such as:
  - gallstones (solid particles that form in the gall bladder),
  - a history of alcoholism,
  - high triglyceride levels;
- you have congestive heart failure, history of any heart problems or other risk factors for heart failure including kidney problems;
- you have any skin problems;
- you have liver problems.

TRAJENTA is not recommended for children and adolescents under 18 years.

Cases of inflammation of the pancreas (**pancreatitis**) have been reported in patients taking TRAJENTA. Pancreatitis can be severe and lead to death.

Cases of **severe skin reactions** including **bullous pemphigoid** can occur and have been reported in patients taking TRAJENTA. You may need treatment in a hospital. You may need to see a dermatologist to diagnose and treat these skin reactions.

**Driving and using machines:** TRAJENTA can cause low blood sugar. This is more likely when you take it with sulfonylurea or with insulin. Before doing these kinds of tasks wait until you know how you respond to TRAJENTA.

### INTERACTIONS WITH THIS MEDICATION

Tell your physician or pharmacist about all the drugs you take. This includes prescription and non-prescription drugs, vitamins, and herbal supplements. TRAJENTA may interact with other medications. This may cause serious side effects. This can be less control of your blood sugar or low blood sugar.

### PROPER USE OF THIS MEDICATION

Take all medicines to control blood sugar as prescribed. Your doctor may lower the amount of sulfonylurea or insulin that you take.

#### Usual Adult Dose:

5 mg tablet, once a day. You can take TRAJENTA with or

without food.

**Overdose:**

If you think you have taken too much TRAJENTA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

- If you forget to take a dose of TRAJENTA, take it as soon as you remember. If you do not remember until it is the time for your next dose, skip the missed dose and go back to your regular schedule.
- Do not take a double dose of TRAJENTA on the same day.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

These are not all the possible side effects that you may have when taking TRAJENTA. If you experience any side effects not listed here, contact your healthcare professional.

Side effects with TRAJENTA include:

- Cough
- Inflamed nose or throat (nasopharyngitis), sore throat, cold symptoms, stuffy or runny nose
- High blood triglyceride
- High blood lipase or amylase
- Constipation
- Hives or nettle rash (urticaria)
- Rash, itching
- Mouth sores (mouth ulceration)

Your doctor may do blood tests before you start TRAJENTA and while you take it. They may check your blood sugar, liver function, and how well your kidneys are working. Your doctor will decide when to perform blood tests and will interpret the results.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<b>Very Common</b>			
<b>Hypoglycemia (low blood sugar – when used with a sulfonylurea):</b> shaking, sweating, anxiety, blurred vision, tingling lips, paleness, mood change, vagueness or confusion		✓	

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<b>Uncommon</b>			
<b>Hypersensitivity (allergic reactions):</b> rash, hives, and swelling of the face, lips, mouth, tongue or throat that may cause difficulty in breathing or swallowing and wheezing and shortness of breath			✓
<b>Rare</b>			
<b>Pancreatitis (inflammation of the pancreas):</b> prolonged severe abdominal pain which may be accompanied by vomiting; pain may spread out towards the back			✓
<b>Severe skin reactions including bullous pemphigoid:</b> redness, peeling skin, and/or blistering of the skin, lips, eyes or mouth			✓
<b>Very Rare</b>			
<b>Rhabdomyolysis (breakdown of damaged muscle):</b> muscle spasms, weakness, red-brown (tea-coloured) urine			✓
<b>Unknown</b>			
<b>Arthralgia:</b> severe joint pain		✓	

*If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.*

**HOW TO STORE IT**

Store at room temperature (15°C to 30°C).

Keep TRAJENTA and all medicines safely away from children.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION****If you want more information about TRAJENTA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), the manufacturer's website (<https://www.boehringer-ingenelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at 1-800-263-5103, extension 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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