

PART III: CONSUMER INFORMATION

Pr. **Trajenta**[®]
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.

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 are taking insulin because TRAJENTA is not approved for use with insulin;
- you are taking an anti-diabetic medicine known as 'sulfonylurea', your doctor may want to reduce your dose of sulfonylurea when you take it together with TRAJENTA in order to avoid low blood sugar;
- 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 congestive heart failure or any heart problems;
- you have any skin problems;
- you have liver problems.

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

INTERACTIONS WITH THIS MEDICATION

Talk to your doctor or pharmacist about all the medicines you take. This includes prescription and non-prescription medicines, and herbal supplements.

PROPER USE OF THIS MEDICATION**Usual dose:**

The adult dose is one 5 mg tablet, once daily, taken with or without food.

Overdose:

In case of drug overdose, contact a healthcare practitioner, 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. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, TRAJENTA can cause side effects. Side effects with TRAJENTA include:

Very Common:

- Low blood sugar (hypoglycemia) when taken with a sulfonylurea. You should stop taking TRAJENTA and see

your doctor immediately if you experience symptoms of low blood sugar such as trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change, vagueness or confusion.

Uncommon:

- Cough;
- Inflamed nose or throat (nasopharyngitis);
- High blood triglyceride;
- Severe allergic reaction (hypersensitivity);
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema);
- Hives or nettle rash (urticaria).

Rare:

- Inflammation of pancreas (pancreatitis);
- Rash;
- Mouth ulceration.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

TRAJENTA can cause abnormal blood test results. 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	
Very Common	Hypoglycemia (when used with a sulfonylurea)		√	√

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	
Uncommon	Allergic reactions including such symptoms as hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema, urticaria), and wheezing and shortness of breath (bronchial hyperreactivity)		√	√
Rare	Pancreatitis: symptoms of pancreatitis (prolonged severe abdominal pain which may be accompanied by vomiting)		√	√
	Severe skin reactions: skin rashes, redness, peeling skin, and/or blistering of the skin, lips, eyes or mouth		√	√

This is not a complete list of side effects. For any unexpected effects while taking TRAJENTA, contact your doctor or pharmacist.

HOW TO STORE IT

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

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.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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (<http://www.boehringer-ingelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 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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