

PART III: CONSUMER INFORMATION**Pr Jentaduetto®**

Linagliptin/Metformin Hydrochloride Tablets

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

ABOUT THIS MEDICATION**What the medication is used for:**

JENTADUETO is used in addition to diet and exercise to improve blood sugar levels in adults with type 2 diabetes mellitus:

- in patients who are not controlled on metformin alone;
- in patients currently on linagliptin and metformin alone;
- in combination with a sulfonyleurea, in patients who are not controlled on metformin and a sulfonyleurea; OR
- in combination with insulin, in patients who are not controlled on metformin and insulin.

What it does:

JENTADUETO is a prescription medicine that contains 2 diabetes medicines, linagliptin and metformin. Together, these medicines help you to achieve better blood sugar control.

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

Metformin is a member of the biguanide class of medicines. It helps to lower the amount of sugar made by the liver and helps to lower the amount of sugar your intestines absorb.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and/or does not use the insulin that your body produces as well as it should. When this happens, sugar (glucose) builds up in the blood. This can lead to serious problems.

When it should not be used:

Do not take JENTADUETO if you:

- are allergic (hypersensitive) to linagliptin, metformin or any of the ingredients in JENTADUETO. See "What the non-medical ingredients are";
- have type 1 diabetes (your body does not produce any insulin);
- have liver or kidney problems;
- have a history of lactic acidosis;
- have metabolic acidosis (including diabetic ketoacidosis, history of ketoacidosis or lactic acidosis – too much acid in the blood);

- are going to get or receive an injection of dye or contrast agent for an x-ray procedure. Talk to your physician or pharmacist about when to stop JENTADUETO and when to start again;
- are stressed, have severe infections, are experiencing trauma, prior to surgery or during the recovery phase;
- have severe heart problems or heart failure;
- have a lack of oxygen in the blood. This is called hypoxemia. This can happen when you have conditions that affect your heart or breathing;
- are dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea, or sweat a lot with activity or exercise and do not drink enough fluids;
- drink a lot of alcohol, regularly or occasionally (binge drinking);
- are breastfeeding (nursing a child);
- are pregnant or planning to become pregnant.

What the medicinal ingredients are:

Linagliptin and metformin hydrochloride

What the important non-medical ingredients are:

JENTADUETO tablets contain the following non-medical ingredients: arginine, colloidal silicon dioxide, copovidone, magnesium stearate, maize starch. In addition, the film coating contains the following inactive ingredients: hypromellose, iron oxide red, iron oxide yellow, propylene glycol, talc, titanium dioxide.

What dosage forms it comes in:

JENTADUETO tablets contain linagliptin/metformin hydrochloride 2.5 mg/500 mg, 2.5 mg/850 mg, or 2.5 mg/1000 mg.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

Lactic acidosis is a rare but serious buildup of acid in the blood. It can cause death. It must be treated in the hospital. JENTADUETO contains a drug called metformin hydrochloride. If you build up too much metformin in your blood you are at risk for lactic acidosis.

Alcohol increases the risk of lactic acidosis caused by metformin. Do not "binge" drink or drink alcohol often when you are taking JENTADUETO.

Lactic Acidosis

Stop taking JENTADUETO if you get any of the following symptoms, which could be signs of lactic acidosis:

- feel very weak or tired;
- have unusual (not normal) muscle pain;
- have trouble breathing;
- have unusual sleepiness or sleep longer than usual;
- have sudden stomach or intestinal problems with nausea and vomiting or diarrhea;

- feel cold, especially in your arms and legs;
- feel dizzy or light-headed;
- have a slow or irregular heartbeat;
- your medical condition suddenly changes.

You have a higher chance of getting lactic acidosis if you:

- have severe kidney problems. Your kidneys can be affected by certain x-ray tests that use injected dye. JENTADUETO is usually stopped before and for two days after such a test. Your doctor should discuss this with you;
- have liver problems;
- have congestive heart failure that requires treatment with medicines;
- drink alcohol very often, or drink a lot of alcohol in short-term (“binge” drinking);
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids;
- have certain x-ray tests with dyes or contrast agents that are injected into your body;
- have surgery;
- have a heart attack, severe infection, or stroke;
- are 80 years of age or older and have not been assessed for kidney function;
- take other medications.

BEFORE or while taking JENTADUETO talk to your physician or pharmacist if you:

- are older than 65 years of age;
- take sulfonylurea or insulin. When JENTADUETO is used in combination with sulfonylurea or insulin, low blood sugar can occur. Your physician may consider lowering the dose of the sulfonylurea or insulin. Take precautions to avoid low blood sugar while driving or using machinery;
- have liver problems;
- 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;
- have any skin problems;
- you have heart problems including congestive heart failure (a condition where your heart becomes weaker and less able to pump the blood that your body needs);
- you have or have had severe kidney problems;
- had an organ transplant;
- have human immunodeficiency syndrome (HIV);
- have any other medical condition including: Vitamin B₁₂ deficiency or anemia or hypothyroidism (low levels of thyroid hormones).

JENTADUETO is not recommended for children and adolescents under 18 years of age.

Cases of inflammation of the pancreas (**pancreatitis**) have been reported in patients taking JENTADUETO. 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 JENTADUETO. 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: JENTADUETO can cause low blood sugar. This is more likely when you take it with sulfonylurea or insulin. Before doing these kinds of tasks wait until you know how you respond to JENTADUETO.

INTERACTIONS WITH THIS MEDICATION

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

This includes prescription and non-prescription drugs, vitamins, and herbal supplements. JENTADUETO may interact with other medications. This may cause serious side effects. This can be less control of your blood sugar or low blood sugar.

If you start any new medicine, tell your healthcare professional.

The following may interact with JENTADUETO:

- rifampin;
- other diabetes drugs such as glyburide;
- furosemide;
- nifedipine (used to treat high blood pressure and chest pain);
- certain “blood thinners” (phenprocoumon or other vitamin K anticoagulants);
- cationic drugs (e.g. amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin);
- Other drugs that tend to produce high blood sugar (hyperglycemia) and may lead to a loss of blood sugar control. Some example of drugs that can increase the blood sugar include:
 - thiazide and other diuretics (water pills);
 - corticosteroids (used to treat joint pain and swelling);
 - phenothiazines (antipsychotic medicine);
 - thyroid products;
 - estrogens or estrogens plus progestogen (female hormones);
 - oral contraceptives (birth control pills);
 - phenytoin (used to treat epilepsy);
 - nicotinic acid (used to prevent and treat niacin deficiency);
 - sympathomimetics (used for heart problems);
 - calcium channel blocking drugs (used for high blood pressure);
 - isoniazid (used to treat tuberculosis);
 - beta-2-agonists (used to treat breathing problems);
 - carbonic anhydrase inhibitors.
- ACE inhibitors drugs may lower blood glucose and the combination with JENTADUETO should be carefully monitored.

PROPER USE OF THIS MEDICATION

Your doctor will individualize your starting dose of JENTADUETO based on your current treatment regimen. Take JENTADUETO exactly as your physician has prescribed. Your physician will tell you how many JENTADUETO tablets to take and how often you should take them.

Your physician may adjust your dose, if needed to further control your blood sugar level.

Usual Adult Dose:

JENTADUETO should be given 2 times a day by mouth with meal to lower your chance of an upset stomach.

Continue to take JENTADUETO as long as your physician prescribes it so you can continue to help control your blood sugar.

You may need to stop JENTADUETO for a short time. Call your physician for instructions if you:

- have a condition that may be associated with dehydration (large loss of body fluids) such as being sick with severe vomiting, diarrhea or fever, or if you drink fluids a lot less than normal;
- plan to have surgery;
- are going to get or receive an injection of dye or contrast agent for an x-ray procedure.

Overdose:

If you think you have taken too much JENTADUETO, 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 JENTADUETO, 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 JENTADUETO at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Side effects with JENTADUETO include:

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

- Gastrointestinal symptoms: diarrhea, constipation, nausea, vomiting, abdominal bloating, upset stomach, gas and loss of appetite
- High blood triglyceride
- Mouth sores (mouth ulceration)

JENTADUETO can cause abnormal blood test results. Your physician will do blood tests before you start JENTADUETO and while you take it. They may check your blood sugar, liver and thyroid function, amount of vitamin B12 and how well your kidneys are working. Your doctor will decide when to perform blood tests and will interpret the results.

Your skin may be more sensitive to sunlight when you take JENTADUETO. Protect your skin from the sun.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	Only if severe	In all cases	
Very Common			
Hypoglycemia (low blood sugar when used with a sulfonylurea or insulin): shaking, sweating, rapid heartbeat, hunger, headache, anxiety, change in vision, tingling lips, paleness, mood change, vagueness or confusion		✓	
Common			
Hypersensitivity (allergic reactions): 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			✓
Rare			
Lactic Acidosis (high level of lactic acid in the blood): malaise or feeling of general discomfort, feeling very weak or tired, low blood pressure, uneasiness or pain, unusual muscle pain, trouble breathing, unusual sleepiness or sleeping longer than usual, sudden stomach or intestinal problems with nausea and vomiting or diarrhea, feeling cold especially in your arms and legs, feeling dizzy or light-headed or suddenly developing a slow or irregular heartbeat			✓

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

Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	Only if severe	In all cases	
Pancreatitis (inflammation of the pancreas): prolonged severe abdominal pain which may be accompanied by vomiting; pain may spread out towards the back			✓
Severe skin reactions including bullous pemphigoid: redness, peeling skin, and/or blistering of the skin, lips, eyes or mouth			✓
Hemolytic anemia (when red blood cells are destroyed faster than bone marrow can replace them): fatigue, pale colour, rapid heartbeat, shortness of breath, dark urine, chills, and backache			✓
Encephalopathy (disease of the brain that severely alters thinking): muscle weakness in one area, poor decision-making or concentration, involuntary twitching, trembling, difficulty speaking or swallowing, seizures			✓
Peripheral neuropathy (a result of damage to your peripheral nerves): gradual onset of numbness, prickling or tingling in your feet or hands, which can spread upward into your legs and arms, sharp, jabbing, throbbing, freezing or burning pain, extreme sensitivity to touch, lack of coordination and falling, muscle weakness or paralysis if motor nerves are affected			✓
Hypothyroidism (low levels of thyroid hormone): fatigue, feeling cold, dry skin, poor memory and concentration, weight gain		✓	
Very Rare			
Vitamin B₁₂ deficiency (decreased vitamin B₁₂ levels in the blood): fatigue, shortness of breath, tingling or numbness of the fingers or toes, difficulty walking properly, irritability, confusion, tender calves		✓	
Hepatitis (inflammation of the liver) or liver disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle spasms, weakness, red-brown (tea-coloured) urine			✓

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

Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	Only if severe	In all cases	
Unknown			
Arthralgia: 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 JENTADUETO 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 JENTADUETO:

- 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-ingelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at 1-800-263-5103, extension 84633.

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