

PART III: CONSUMER INFORMATIONPr **Jentaduetto**TM

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

- in patients who are not controlled on metformin alone;
- in patients currently on linagliptin (TRAJENTA) and metformin alone; OR
- in combination with a sulfonylurea, in patients who are not controlled on metformin and a sulfonylurea.

What it does:

JENTADUETO is a prescription medicine that contains 2 diabetes medicines, linagliptin and metformin.

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.

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:

You should not take JENTADUETO if you:

- are allergic (hypersensitive) to linagliptin, metformin or any of the non-medicinal ingredients in JENTADUETO. See "**What the important non-medicinal 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 or diabetic ketoacidosis (increased ketones in the blood or urine)
- have certain x-ray tests with dyes or contrast agents that are injected into your body

- are stressed, have severe infections, are experiencing trauma, prior to surgery or during the recovery phase
- have cardiovascular collapse (abrupt failure of blood circulation) or cardiorespiratory insufficiency
- 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 breast-feeding
- are pregnant or planning to become pregnant

What the medicinal ingredients are:

linagliptin and metformin hydrochloride

What the important non-medicinal ingredients are:

JENTADUETO tablets contain the following non-medicinal 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 is supplied as tablets containing 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**

JENTADUETO contains metformin which can rarely cause lactic acidosis. Lactic acidosis can cause death and must be treated in the hospital (see section *Lactic Acidosis* below). Therefore, you should not drink a lot of alcohol if you take JENTADUETO (see section *Lactic Acidosis* below).

Lactic Acidosis

Stop taking JENTADUETO and call your doctor right away 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 lightheaded
- have a slow or irregular heartbeat

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

- have kidney problems. People whose kidneys are not working properly should not take JENTADUETO.

- 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

BEFORE you use JENTADUETO talk to your doctor or pharmacist if you:

- are taking insulin because JENTADUETO is not approved for use with insulin
- have kidney problems
- have an injection of dye or contrast agents for an x-ray procedure
- have liver problems
- have pancreas problems, such as inflammation of the pancreas
- have any skin problems
- have had allergic reaction to any other medicines that you take to control the blood sugar
- have heart problems, including congestive heart failure
- drink alcohol very often, or drink a lot of alcohol in short term (“binge” drinking)
- have any other medical conditions
- are pregnant or planning to become pregnant
- are breast-feeding or plan to breast-feed

INTERACTIONS WITH THIS MEDICATION

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

Some drugs may interact with JENTADUETO. Tell your doctor if you are taking:

- rifampin
- other diabetes drugs such as glyburide
- furosemide
- nifedipine
- certain blood thinners (anticoagulants)
- cationic drugs (e.g. amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin)
- drugs that can increase the blood sugar include:
 - thiazide and other diuretics (water pills)
 - corticosteroids (e.g. Prednisone)

- phenothiazines
- thyroid products
- estrogens or estrogens plus progestogen
- oral contraceptives (birth control pills)
- phenytoin
- nicotinic acid
- sympathomimetics
- calcium channel blocking drugs
- isoniazid
- beta-2-agonists
- angiotensin converting enzyme (ACE) inhibitors. ACE inhibitors may lower blood glucose.

PROPER USE OF THIS MEDICATION

Usual adult dose:

2.5/500 mg, or 2.5/850 mg, or 2.5/1000 mg twice daily taken with meals. Take JENTADUETO tablet with meals to lower the chance of having an upset stomach.

Overdose:

If you take more JENTADUETO tablets than you should or in case of drug overdose, contact your doctor or a poison control centre or go to the emergency room of the hospital near you.

Missed dose:

- If you forget to take a dose of JENTADUETO, 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 of JENTADUETO at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, JENTADUETO can cause side effects.

The most common side effects of JENTADUETO include:

- Stuffy nose or runny nose and sore throat (nasopharyngitis)
- Diarrhea, nausea, and stomach upset, bloating, flatulence

Other side effects include:

- Allergic (hypersensitivity) reactions: Allergic reactions such as rash, hives, and swelling of the face, lips, and throat, or coughing, wheezing, or shortness of breath may rarely occur. If you have these symptoms, stop taking JENTADUETO and call your doctor right away
- Pancreatitis
- Lactic Acidosis, a build-up of lactic acid in the blood that can cause death. You should stop taking JENTADUETO and call your doctor right away if you have any signs of lactic acidosis (see section above **Lactic Acidosis**). Lactic acidosis is a medical emergency and must be treated in the hospital.
- Low blood sugar (hypoglycemia): If you take JENTADUETO with another medication that can cause

low blood sugar, such as sulfonylureas, you have a higher risk of having low blood sugar. If you have symptoms of low blood sugar, you should check your blood sugar and treat it, then call your doctor. Symptoms of low blood sugar include: shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.

- 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.

JENTADUETO 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	
Rare	<p>Lactic Acidosis: symptoms include feeling very weak or tired, unusual (not normal) 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 lightheaded or suddenly developing a slow or irregular heartbeat</p> <p>Pancreatitis: symptoms include prolonged severe abdominal pain which may be accompanied by vomiting</p> <p>Blistering of skin</p>		√	√
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This is not a complete list of side effects. For any unexpected effects while taking JENTADUETO, contact your doctor or pharmacist.

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)		√	
Uncommon	<p>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)</p>		√	√
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HOW TO STORE IT

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.boehringer-ingenlheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

Please check our website to see if more up-to-date information has been posted.

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