HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use JENTADUETO safely and effectively. See full prescribing information for JENTADUETO.

Jentadueto™ (linagliptin and metformin hydrochloride) tablets
Initial U.S. Approval: 2012

WARNING: RISK OF LACTIC ACIDOSIS

See full prescribing information for complete boxed warning.

- **Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure. (5.1)**
- **Symptoms include malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate. (5.1)**
- **If acidosis is suspected, discontinue JENTADUETO and hospitalize the patient immediately (5.1)**

----------RECENT MAJOR CHANGES----------

Indications and Usage	
Important Limitations of Use (1.2)	6/2013
Warnings and Precautions	
Pancreatitis (5.2)	6/2013

----------INDICATIONS AND USAGE----------

JENTADUETO is a dipeptidyl peptidase-4 (DPP-4) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate (1.1)

Important limitations of use:

- Not for treatment of type 1 diabetes or diabetic ketoacidosis (1.2)
- Has not been studied in combination with insulin (1.2)
- Has not been studied in patients with a history of pancreatitis (1.2)

----------DOSAGE AND ADMINISTRATION----------

- Individualize the starting dose of JENTADUETO based on the patient's current regimen (2.1)
- The maximum recommended dose is 2.5 mg linagliptin/1000 mg metformin twice daily (2.1)
- Should be given twice daily with meals, with gradual dose escalation to reduce the gastrointestinal side effects due to metformin (2.1)

----------DOSAGE FORMS AND STRENGTHS----------

Tablets:
2.5 mg linagliptin/500 mg metformin hydrochloride
2.5 mg linagliptin/850 mg metformin hydrochloride
2.5 mg linagliptin/1000 mg metformin hydrochloride (3)

----------CONTRAINDICATIONS----------

- Renal impairment (4)
- Metabolic acidosis, including diabetic ketoacidosis (4)
- Hypersensitivity to linagliptin or metformin (4)

----------WARNINGS AND PRECAUTIONS----------

- Lactic acidosis: Warn against excessive alcohol use. JENTADUETO is not recommended in hepatic impairment or hypoxic states and is contraindicated in renal impairment. Ensure normal renal function before initiating and at least annually thereafter. (5.1, 5.3, 5.4, 5.7, 5.8)
- There have been postmarketing reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, promptly discontinue JENTADUETO. (5.2)
- Temporarily discontinue JENTADUETO in patients undergoing radiologic studies with intravascular administration of iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids (5.3)
- Hypoglycemia: When used with a sulfonylurea (SU), a lower dose of the SU may be required to reduce the risk of hypoglycemia (2.2, 5.5)
- Vitamin B_{12} deficiency: Metformin may lower vitamin B_{12} levels. Monitor hematologic parameters annually. (5.6)
- Macrovascular outcomes: No conclusive evidence of macrovascular risk reduction with JENTADUETO or any other antidiabetic drug (5.9)

----------ADVERSE REACTIONS----------

- Adverse reactions reported in ≥5% of patients treated with JENTADUETO and more commonly than in patients treated with placebo are nasopharyngitis and diarrhea (6.1)
- Hypoglycemia was more commonly reported in patients treated with the combination of JENTADUETO, and SU compared with those treated with the combination of SU and metformin (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257 or 1-800-459-9906 TTY, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

- Cationic drugs eliminated by renal tubular secretion: May reduce metformin elimination. Use with caution. (7.1)
- P-glycoprotein/CYP3A4 inducer: The efficacy of JENTADUETO may be reduced when administered in combination (e.g., rifampin). Use of alternative treatments is strongly recommended. (7.2)

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: There are no adequate and well-controlled studies in pregnant women. JENTADUETO tablets should be used during pregnancy only if clearly needed. (8.1)
- Nursing mothers: Caution should be exercised when JENTADUETO is administered to a nursing woman (8.3)
- Pediatric patients: Safety and effectiveness of JENTADUETO in patients below the age of 18 have not been established (8.4)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 6/2013

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FULL PRESCRIBING INFORMATION

WARNING: RISK OF LACTIC ACIDOSIS

Lactic acidosis is a rare, but serious, complication that can occur due to metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure.

The onset is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress.

Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.

If acidosis is suspected, JENTADUETO should be discontinued and the patient hospitalized immediately. *[See Warnings and Precautions (5.1).]*

1 INDICATIONS AND USAGE

1.1 Indication

JENTADUETO tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate *[see Dosage and Administration (2.1) and Clinical Studies (14.1)]*.

1.2 Important Limitations of Use

JENTADUETO should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

JENTADUETO has not been studied in combination with insulin.

JENTADUETO has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO. *[see Warnings and Precautions (5.2)]*

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The dosage of JENTADUETO should be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended dose of 2.5 mg linagliptin/1000 mg metformin hydrochloride twice daily. JENTADUETO should be given twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal (GI) side effects associated with metformin use. For available dosage forms and strengths see *[Dosage Forms and Strengths (3)]*.

Recommended starting dose:

- In patients currently not treated with metformin, initiate treatment with 2.5 mg linagliptin/500 mg metformin hydrochloride twice daily
- In patients already treated with metformin, start with 2.5 mg linagliptin and the current dose of metformin taken at each of the two daily meals (e.g., a patient on metformin 1000 mg twice daily would be started on 2.5 mg linagliptin/1000 mg metformin hydrochloride twice daily with meals).
- Patients already treated with linagliptin and metformin individual components may be switched to JENTADUETO containing the same doses of each component.

No studies have been performed specifically examining the safety and efficacy of JENTADUETO in patients previously treated with other oral antihyperglycemic agents and switched to JENTADUETO. Any change in therapy of type 2 diabetes mellitus should be undertaken with care and appropriate monitoring as changes in glycemic control can occur.

2.2 Concomitant Use With Sulfonylurea

When JENTADUETO is used in combination with an insulin secretagogue (e.g., sulfonylurea), a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia *[see Warnings and Precautions (5.5)]*.

3 DOSAGE FORMS AND STRENGTHS

JENTADUETO is a combination of linagliptin and metformin hydrochloride. JENTADUETO tablets are available in the following dosage forms and strengths:

- 2.5 mg linagliptin/500 mg metformin hydrochloride tablets are light yellow, oval, biconvex tablets debossed with “D2/500” on one side and the Boehringer Ingelheim logo on the other side
- 2.5 mg linagliptin/850 mg metformin hydrochloride tablets are light orange, oval, biconvex tablets debossed with “D2/850” on one side and the Boehringer Ingelheim logo on the other side
- 2.5 mg linagliptin/1000 mg metformin hydrochloride tablets are light pink, oval, biconvex tablets debossed with “D2/1000” on one side and the Boehringer Ingelheim logo on the other side

4 CONTRAINDICATIONS

JENTADUETO is contraindicated in patients with:

- Renal impairment (e.g., serum creatinine ≥1.5 mg/dL for men, ≥1.4 mg/dL for women, or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia *[see Warnings and Precautions (5.1, 5.3)]*
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin *[see Warnings and Precautions (5.1)]*
- A history of hypersensitivity reaction to linagliptin (such as urticaria, angioedema, or bronchial hyperreactivity) or metformin *[see Adverse Reactions (6.1)]*

5 WARNINGS AND PRECAUTIONS

5.1 Lactic Acidosis

Metformin

Lactic acidosis is a serious, metabolic complication that can occur due to metformin accumulation during treatment with JENTADUETO and is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus, and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels (>5 mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When metformin is implicated as the cause of lactic acidosis, metformin plasma levels of >5 µg/mL are generally found.

The reported incidence of lactic acidosis in patients receiving metformin is approximately 0.03 cases/1000 patient-years, (with approximately 0.015 fatal cases/1000 patient-years). In more than 20,000 patient-years exposure to metformin in clinical trials, there were no reports of lactic acidosis. Reported cases have occurred primarily in diabetic patients with significant renal impairment, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications. Patients with congestive heart failure requiring pharmacologic management, particularly when accompanied by hypoperfusion and hypoxemia due to unstable or acute failure, are at increased risk of lactic acidosis. The risk of lactic acidosis increases with the degree of renal impairment and the patient's age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking metformin. In particular, treatment of the elderly should be accompanied by careful monitoring of renal function. Metformin treatment should not be initiated in any patients unless measurement of creatinine clearance demonstrates that renal function is not reduced. In addition, metformin should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis. Because impaired hepatic function may significantly limit the ability to clear lactate, metformin should be avoided in patients with clinical or laboratory evidence of hepatic impairment. Patients should be cautioned against excessive alcohol intake when taking metformin, since alcohol potentiates the effects of metformin on lactate metabolism. In addition, metformin should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure necessitating restricted intake of food or fluids. Use of topiramate, a carbonic anhydrase inhibitor, in epilepsy and migraine prophylaxis may cause dose-dependent metabolic acidosis and may exacerbate the risk of metformin-induced lactic acidosis *[see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]*.

The onset of lactic acidosis is often subtle, and accompanied by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. More severe acidosis may be associated with signs such as hypothermia, hypotension, and resistant bradyarrhythmias. Patients should be educated to recognize and promptly report these symptoms. If present, JENTADUETO should be discontinued until lactic acidosis is ruled out. Gastrointestinal symptoms, which are commonly reported during initiation of metformin therapy are less frequently observed in subjects on a chronic, stable, dose of metformin. Gastrointestinal symptoms in subjects on chronic, stable, dose of metformin could be caused by lactic acidosis or other serious disease.

To rule out lactic acidosis, serum electrolytes, ketones, blood glucose, blood pH, lactate levels, and blood metformin levels may be useful. Levels of fasting venous plasma lactate above the upper limit of normal but less than 5 mmol/L in patients taking metformin do not necessarily indicate impending lactic acidosis and may be due to other mechanisms, such as poorly-controlled diabetes or obesity, vigorous physical activity, or technical problems in sample handling.

Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonemia). Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking metformin, the drug should be discontinued immediately and supportive measures promptly instituted. Metformin is dialyzable (clearance of up to 170 mL/min under good hemodynamic conditions) and prompt hemodialysis is recommended to remove the accumulated metformin and correct the metabolic acidosis. Such management often results in prompt reversal of symptoms and recovery *[see Boxed Warning]*.

5.2 Pancreatitis

There have been postmarketing reports of acute pancreatitis, including fatal pancreatitis, in patients taking linagliptin. Take careful notice of potential signs and symptoms of pancreatitis. If pancreatitis is suspected, promptly discontinue JENTADUETO and initiate appropriate management. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JENTADUETO.

5.3 Monitoring of Renal Function

Although linagliptin undergoes minimal renal excretion, metformin is known to be substantially excreted by the kidney. The risk of metformin accumulation and lactic acidosis increases with the degree of renal impairment. Therefore, JENTADUETO is contraindicated in patients with renal impairment.

Before initiation of therapy with JENTADUETO and at least annually thereafter, renal function should be assessed and verified to be normal. In patients in whom development of renal impairment is anticipated (e.g., elderly), renal function should be assessed more frequently and JENTADUETO discontinued if evidence of renal impairment is present.

Linagliptin may be continued as a single entity tablet at the same total daily dose of 5 mg if JENTADUETO is discontinued due to evidence of renal impairment. No dose adjustment of linagliptin is recommended in patients with renal impairment.

Use of concomitant medications that may affect renal function or metformin disposition:

Concomitant medication(s) that may affect renal function or result in significant hemodynamic change or interfere with the disposition of metformin should be used with caution *[see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]*.

Radiological studies and surgical procedures:

Radiologic studies involving the use of intravascular iodinated contrast materials (e.g., intravenous urogram, intravenous cholangiography, angiography, and computed tomography) can lead to acute alteration of renal function and have been associated with lactic acidosis in patients receiving metformin. Therefore, in patients in whom any such study is planned, JENTADUETO should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been confirmed to be normal.

JENTADUETO should be temporarily discontinued for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal.

5.4 Impaired Hepatic Function

Because impaired hepatic function has been associated with some cases of lactic acidosis with metformin therapy, JENTADUETO should generally be avoided in patients with clinical or laboratory evidence of hepatic disease *[see Warnings and Precautions (5.1)]*.

5.5 Hypoglycemia

Linagliptin

Insulin secretagogues are known to cause hypoglycemia. The use of linagliptin in combination with an insulin secretagogue (e.g., sulfonylurea) was associated with a higher rate of hypoglycemia compared with placebo in a clinical trial *[see Adverse Reactions (6.1)]*. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with JENTADUETO *[see Dosage and Administration (2.2)]*.

Metformin

Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use, but could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitant use with other glucose-lowering agents (such as SUs and insulin) or ethanol. Elderly, debilitated, or malnourished patients, and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects. Hypoglycemia may be difficult to recognize in the elderly, and in people who are taking β-adrenergic blocking drugs.

5.6 Vitamin B_{12} Levels

In controlled, 29-week clinical trials of metformin, a decrease to subnormal levels of previously normal serum vitamin B_{12} levels, without clinical manifestations, was observed in approximately 7% of metformin-treated patients. Such decrease, possibly due to interference with B_{12} absorption from the B_{12}-intrinsic factor complex, is, however, very rarely associated with anemia or neurologic manifestations due to the short duration (<1 year) of the clinical trials. This risk may be more relevant to patients receiving long-term treatment with metformin, and adverse hematologic and neurologic reactions have been reported postmarketing. The decrease in vitamin B_{12} levels appears to be rapidly reversible with discontinuation of metformin or vitamin B_{12} supplementation. Measurement of hematologic parameters on an annual basis is advised in patients on JENTADUETO and any apparent abnormalities should be appropriately investigated and managed. Certain individuals (those with inadequate vitamin B_{12} or calcium intake or absorption) appear to be predisposed to developing subnormal vitamin B_{12} levels. In these patients, routine serum vitamin B_{12} measurement at 2- to 3-year intervals may be useful.

5.7 Alcohol Intake

Alcohol is known to potentiate the effect of metformin on lactate metabolism. Patients, therefore, should be warned against excessive alcohol intake while receiving JENTADUETO *[see Warnings and Precautions (5.1)]*.

5.8 Hypoxic States

Cardiovascular collapse (shock) from whatever cause (e.g., acute congestive heart failure, acute myocardial infarction, and other conditions characterized by hypoxemia) have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients on JENTADUETO therapy, the drug should be promptly discontinued *[see Warnings and Precautions (5.1)]*.

5.9 Macrovascular Outcomes

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with linagliptin or metformin or any other antidiabetic drug.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Linagliptin/Metformin

The safety of concomitantly administered linagliptin (daily dose 5 mg) and metformin (mean daily dose of approximately 1800 mg) has been evaluated in 2816 patients with type 2 diabetes mellitus treated for ≥12 weeks in clinical trials.

Three placebo-controlled studies with linagliptin + metformin were conducted: 2 studies were 24 weeks in duration, 1 study was 12 weeks in duration. In the 3 placebo-controlled clinical studies, adverse events which occurred in ≥5% of patients receiving linagliptin + metformin (n=875) and were more common than in patients given placebo + metformin (n=539) included nasopharyngitis (5.7% vs 4.3%).

In a 24-week factorial design study, adverse events reported in ≥5% of patients receiving linagliptin + metformin and were more common than in patients given placebo are shown in Table 1.

Table 1 Adverse Reactions Reported in ≥5% of Patients Treated with Linagliptin + Metformin and Greater than with Placebo in a 24-week Factorial-Design Study

	Placebo n=72	**Linagliptin Monotherapy n=142**	**Metformin Monotherapy n=291**	**Combination of Linagliptin with Metformin n=286**
	n (%)	**n (%)**	**n (%)**	**n (%)**
Nasopharyngitis	1 (1.4)	8 (5.6)	8 (2.7)	18 (6.3)
Diarrhea	2 (2.8)	5 (3.5)	11 (3.8)	18 (6.3)

Other adverse reactions reported in clinical studies with treatment of linagliptin + metformin were hypersensitivity (e.g., urticaria, angioedema, or bronchial hyperactivity), cough, decreased appetite, nausea, vomiting, pruritus, and pancreatitis.

Linagliptin Monotherapy

Nasopharyngitis was reported in ≥5% of patients treated with linagliptin and more commonly than in patients treated with placebo (5.8% vs 5.5%). In the clinical trial program, pancreatitis was reported in 8 of 4687 patients (4311 patient-years of exposure) while being treated with TRADJENTA compared with 0 of 1183 patients (433 patient-years of exposure) treated with placebo. Three additional cases of pancreatitis were reported following the last administered dose of linagliptin.

Other adverse reactions reported in clinical studies with treatment of linagliptin monotherapy were hypersensitivity (e.g., urticaria, angioedema, localized skin exfoliation, or bronchial hyperactivity) and myalgia.

Metformin Monotherapy

The most common adverse reactions due to initiation of metformin are diarrhea, nausea/vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.

Long-term treatment with metformin has been associated with a decrease in vitamin B_{12} absorption which may very rarely result in clinically significant vitamin B_{12} deficiency (e.g., megaloblastic anemia) *[see Warnings and Precautions (5.5)]*.

Hypoglycemia

In a 24-week factorial design study, hypoglycemia was reported in 4 (1.4%) of 286 subjects treated with linagliptin + metformin, 6 (2.1%) of 291 subjects treated with metformin, and 1 (1.4%) of 72 subjects treated with placebo. When linagliptin was administered in combination with metformin and a sulfonylurea, 181 (22.9%) of 792 patients reported hypoglycemia compared with 39 (14.8%) of 263 patients administered placebo in combination with metformin and sulfonylurea.

Laboratory Tests

Changes in laboratory findings were similar in patients treated with linagliptin + metformin compared to patients treated with placebo + metformin. Changes in

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