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

TRADJENTA® (linagliptin tablets), for oral use
Initial U.S. Approval: 2011

----------RECENT MAJOR CHANGES----------
Indications and Usage (1) 4/2022

----------INDICATIONS AND USAGE----------
TRADJENTA is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1)

Limitations of Use
- Should not be used in patients with type 1 diabetes (1)
- Has not been studied in patients with a history of pancreatitis (1)

----------DOSAGE AND ADMINISTRATION----------
- The recommended dose of TRADJENTA is 5 mg once daily (2.1)
- TRADJENTA can be taken with or without food (2.1)

----------DOSAGE FORMS AND STRENGTHS----------
Tablets: 5 mg (3)

----------CONTRAINDICATIONS----------
Hypersensitivity to linagliptin or any of the excipients in TRADJENTA (4, 5.3)

----------WARNINGS AND PRECAUTIONS----------
- *Pancreatitis:* There have been reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, promptly discontinue TRADJENTA. (5.1)
- *Hypoglycemia:* Consider lowering the dose of insulin secretagogue or insulin to reduce the risk of hypoglycemia when initiating TRADJENTA (5.2)
- *Hypersensitivity reactions:* Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema, and exfoliative skin conditions) have occurred with TRADJENTA. If hypersensitivity reactions occur, discontinue TRADJENTA, treat promptly, and monitor until signs and symptoms resolve. (5.3)
- *Arthralgia:* Severe and disabling arthralgia has been reported in patients taking DPP-4 inhibitors. Consider as a possible cause for severe joint pain and discontinue drug if appropriate. (5.4)
- *Bullous pemphigoid:* There have been reports of bullous pemphigoid requiring hospitalization. Tell patients to report development of blisters or erosions. If bullous pemphigoid is suspected, discontinue TRADJENTA. (5.5)
- *Heart failure:* Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of TRADJENTA in patients who have known risk factors for heart failure. Monitor for signs and symptoms. (5.6)

----------ADVERSE REACTIONS----------
Adverse reactions reported in ≥5% of patients treated with TRADJENTA and more commonly than in patients treated with placebo included nasopharyngitis (6.1)

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

----------DRUG INTERACTIONS----------
Strong P-glycoprotein/CYP3A4 inducer: The efficacy of TRADJENTA may be reduced when administered in combination (e.g., with rifampin). Use of alternative treatments is strongly recommended. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 4/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

TRADJENTA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

TRADJENTA should not be used in patients with type 1 diabetes as it would not be effective.

TRADJENTA 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 TRADJENTA *[see Warnings and Precautions (5.1)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The recommended dose of TRADJENTA is 5 mg once daily.

TRADJENTA tablets can be taken with or without food.

3 DOSAGE FORMS AND STRENGTHS

TRADJENTA (linagliptin) 5 mg tablets are light red, round, biconvex, bevel-edged, film-coated tablets with “D5” debossed on one side and the Boehringer Ingelheim logo debossed on the other side.

4 CONTRAINDICATIONS

TRADJENTA is contraindicated in patients with hypersensitivity to linagliptin or any of the excipients in TRADJENTA, reactions such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity have occurred *[see Warnings and Precautions (5.3) and Adverse Reactions (6)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Pancreatitis

Acute pancreatitis, including fatal pancreatitis, has been reported in patients treated with TRADJENTA. In the CARMELINA trial *[see Clinical Studies (14)]*, acute pancreatitis was reported in 9 (0.3%) patients treated with TRADJENTA and in 5 (0.1%) patients treated with placebo. Two patients treated with TRADJENTA in the CARMELINA trial had acute pancreatitis with a fatal outcome. There have been postmarketing reports of acute pancreatitis, including fatal pancreatitis, in patients treated with TRADJENTA.

Take careful notice of potential signs and symptoms of pancreatitis. If pancreatitis is suspected, promptly discontinue TRADJENTA 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 TRADJENTA.

5.2 Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues

Insulin secretagogues and insulin are known to cause hypoglycemia. The risk of hypoglycemia is increased when TRADJENTA is used in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin *[see Adverse Reactions (6.1)]*. The use of TRADJENTA in combination with insulin in subjects with severe renal impairment was associated with a higher rate of hypoglycemia *[see Adverse Reactions (6.1)]*. Therefore, a lower dose of the insulin secretagogue or insulin may be required to reduce the risk of hypoglycemia when used in combination with TRADJENTA.

5.3 Hypersensitivity Reactions

There have been postmarketing reports of serious hypersensitivity reactions in patients treated with TRADJENTA. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions. Onset of these reactions occurred predominantly within the first 3 months after initiation of treatment with TRADJENTA, with some reports occurring after the first dose. If a serious hypersensitivity reaction is suspected, discontinue TRADJENTA, assess for other potential causes for the event, and institute alternative treatment for diabetes.

Angioedema has also been reported with other dipeptidyl peptidase-4 (DPP-4) inhibitors. Use caution in a patient with a history of angioedema to another DPP-4 inhibitor because it is unknown whether such patients will be predisposed to angioedema with TRADJENTA.

5.4 Severe and Disabling Arthralgia

There have been postmarketing reports of severe and disabling arthralgia in patients taking DPP-4 inhibitors. The time to onset of symptoms following initiation of drug therapy varied from one day to years. Patients experienced relief of symptoms upon discontinuation of the medication. A subset of patients experienced a recurrence of symptoms when restarting the same drug or a different DPP-4 inhibitor. Consider DPP-4 inhibitors as a possible cause for severe joint pain and discontinue drug if appropriate.

5.5 Bullous Pemphigoid

Bullous pemphigoid was reported in 7 (0.2%) patients treated with TRADJENTA compared to none in patients treated with placebo in the CARMELINA trial *[see Clinical Studies (14)]*, and 3 of these patients were hospitalized due to bullous pemphigoid. Postmarketing cases of bullous pemphigoid requiring hospitalization have been reported with DPP-4 inhibitor use. In reported cases, patients typically recovered with topical or systemic immunosuppressive treatment and discontinuation of the DPP-4 inhibitor. Tell patients to report development of blisters or erosions while receiving TRADJENTA. If bullous pemphigoid is suspected, TRADJENTA should be discontinued and referral to a dermatologist should be considered for diagnosis and appropriate treatment.

5.6 Heart Failure

An association between DPP-4 inhibitor treatment and heart failure has been observed in cardiovascular outcomes trials for two other members of the DPP-4 inhibitor class. These trials evaluated patients with type 2 diabetes mellitus and atherosclerotic cardiovascular disease.

Consider the risks and benefits of TRADJENTA prior to initiating treatment in patients at risk for heart failure, such as those with a prior history of heart failure and a history of renal impairment, and observe these patients for signs and symptoms of heart failure during therapy. Advise patients of the characteristic symptoms of heart failure and to immediately report such symptoms. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuation of TRADJENTA.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below or elsewhere in the prescribing information:

- Pancreatitis *[see Warnings and Precautions (5.1)]*
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues *[see Warnings and Precautions (5.2)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.3)]*
- Severe and Disabling Arthralgia *[see Warnings and Precautions (5.4)]*
- Bullous Pemphigoid *[see Warnings and Precautions (5.5)]*
- Heart Failure *[see Warnings and Precautions (5.6)]*

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 practice.

The safety evaluation of TRADJENTA 5 mg once daily in patients with type 2 diabetes is based on 14 placebo-controlled trials, 1 active-controlled study, and one study in patients with severe renal impairment. In the 14 placebo-controlled studies, a total of 3625 patients were randomized and treated with TRADJENTA 5 mg daily and 2176 with placebo. The mean exposure in patients treated with TRADJENTA across studies was 29.6 weeks. The maximum follow-up was 78 weeks.

TRADJENTA 5 mg once daily was studied as monotherapy in three placebo-controlled trials of 18 and 24 weeks' duration and in five additional placebo-controlled studies lasting ≤18 weeks. The use of TRADJENTA in combination with other antihyperglycemic agents was studied in six placebo-controlled trials: two with metformin (12 and 24 weeks' treatment duration); one with a sulfonylurea (18 weeks' treatment duration); one with metformin and sulfonylurea (24 weeks' treatment duration); one with pioglitazone (24 weeks' treatment duration); and one with insulin (primary endpoint at 24 weeks).

In a pooled dataset of 14 placebo-controlled clinical trials, adverse reactions that occurred in ≥2% of patients receiving TRADJENTA (n = 3625) and more commonly than in patients given placebo (n = 2176), are shown in Table 1.

Table 1 Adverse Reactions Reported in ≥2% of Patients Treated with TRADJENTA and Greater than Placebo in Placebo-Controlled Clinical Studies of TRADJENTA Monotherapy or Combination Therapy

Adverse Reactions	TRADJENTA 5 mg (%) n = 3625	Placebo (%) n = 2176
Nasopharyngitis	7.0	6.1
Diarrhea	3.3	3.0
Cough	2.1	1.4

Rates for other adverse reactions for TRADJENTA 5 mg vs placebo when TRADJENTA was used in combination with specific antidiabetic agents were: urinary tract infection (3.1% vs 0%) and hypertriglyceridemia (2.4% vs 0%) when TRADJENTA was used as add-on to sulfonylurea; hyperlipidemia (2.7% vs 0.8%) and weight increased (2.3% vs 0.8%) when TRADJENTA was used as add-on to pioglitazone; and constipation (2.1% vs 1%) when TRADJENTA was used as add-on to basal insulin therapy. Other adverse reactions reported in clinical studies with treatment of TRADJENTA were hypersensitivity (e.g., urticaria, angioedema, localized skin exfoliation, or bronchial hyperreactivity) and myalgia.

Following 104 weeks' treatment in a controlled study comparing TRADJENTA with glimepiride in which all patients were also receiving metformin, adverse reactions reported in ≥5% of patients treated with TRADJENTA (n = 776) and more frequently than in patients treated with a sulfonylurea (n = 775) were back pain (9.1% vs 8.4%), arthralgia (8.1% vs 6.1%), upper respiratory tract infection (8.0% vs 7.6%), headache (6.4% vs 5.2%), cough (6.1% vs 4.9%), and pain in extremity (5.3% vs 3.9%).

In the clinical trial program, pancreatitis was reported in 15.2 cases per 10,000 patient year exposure while being treated with TRADJENTA compared with 3.7 cases per 10,000 patient year exposure while being treated with comparator (placebo and active comparator, sulfonylurea). Three additional cases of pancreatitis were reported following the last administered dose of linagliptin.

Hypoglycemia

Table 2 summarizes the incidence of hypoglycemia in placebo-controlled studies of TRADJENTA. The incidence of hypoglycemia increased when TRADJENTA was administered with sulfonylurea or insulin.

Table 2: Incidence (%) of Hypoglycemia in Placebo-Controlled Clinical Studies of TRADJENTA in Patients with Type 2 Diabetes Mellitus

Add-on to Sulfonylurea (18 Weeks)	**Placebo (N=84)**	**TRADJENTA (N=161)**
Hypoglycemia with plasma glucose <54 mg/dL (%)	1.2	1.9
Severe* hypoglycemia (%)	0	0
Add-on to Metformin and Sulfonylurea (24 Weeks)	**Placebo (N=263)**	**TRADJENTA (N=792)**
Hypoglycemia with plasma glucose <54 mg/dL (%)	5.3	8.1
Severe* hypoglycemia (%)	0.8	0.6
Add-on to Basal Insulin (52 Weeks)	**Placebo (N=630)**	**TRADJENTA (N=631)**
Hypoglycemia with plasma glucose <54 mg/dL (%)	21.6	19.8
Severe* hypoglycemia (%)	1.1	1.7

*Hypoglycemia requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.

In an active-controlled (glimepiride) cardiovascular safety study with TRADJENTA (CAROLINA) with median time on treatment of 5.9 years, the incidence of severe hypoglycemia was 0.3% in the TRADJENTA group (N=3014) and 2.2% in glimepiride group (N=3000).

Use in Renal Impairment
TRADJENTA was compared to placebo as add-on to pre-existing antidiabetic therapy over 52 weeks in 133 patients with severe renal impairment (estimated GFR <30 mL/min). For the initial 12 weeks of the study, background antidiabetic therapy was kept stable and included insulin, sulfonylurea, glinides, and pioglitazone. For the remainder of the trial, dose adjustments in antidiabetic background therapy were allowed.

In general, the incidence of adverse events including severe hypoglycemia was similar to those reported in other TRADJENTA trials. The observed incidence of hypoglycemia was higher (TRADJENTA, 63% compared to placebo, 49%) due to an increase in asymptomatic hypoglycemic events especially during the first 12 weeks when background glycemic therapies were kept stable. Ten TRADJENTA-treated patients (15%) and 11 placebo-treated patients (17%) reported at least one episode of confirmed symptomatic hypoglycemia (accompanying finger stick glucose ≤54 mg/dL). During the same time period, severe hypoglycemic events, defined as an event requiring the assistance of another person to actively administer carbohydrate, glucagon or other resuscitative actions, were reported in 3 (4.4%) TRADJENTA-treated patients and 3 (4.6%) placebo-treated patients. Events that were considered life-threatening or required hospitalization were reported in 2 (2.9%) patients on TRADJENTA and 1 (1.5%) patient on placebo.

Renal function as measured by mean eGFR and creatinine clearance did not change over 52 weeks' treatment compared to placebo.

Laboratory Tests
Changes in laboratory findings were similar in patients treated with TRADJENTA 5 mg compared to patients treated with placebo.

Increase in Uric Acid: Changes in laboratory values that occurred more frequently in the TRADJENTA group and ≥1% more than in the placebo group were increases in uric acid (1.3% in the placebo group, 2.7% in the TRADJENTA group).

Increase in Lipase: In a placebo-controlled clinical trial with TRADJENTA in type 2 diabetes mellitus patients with micro- or macroalbuminuria, a mean increase of 30% in lipase concentrations from baseline to 24 weeks was observed in the TRADJENTA arm compared to a mean decrease of 2% in the placebo arm. Lipase levels above 3 times upper limit of normal were seen in 8.2% compared to 1.7% patients in the TRADJENTA and placebo arms, respectively.

Increase in Amylase: In a cardiovascular safety study comparing TRADJENTA versus glimepiride in patients with type 2 diabetes mellitus, amylase levels above 3 times upper limit of normal were seen in 1.0% compared to 0.5% of patients in the TRADJENTA and glimepiride arms, respectively.

The clinical significance of elevations in lipase and amylase with TRADJENTA is unknown in the absence of potential signs and symptoms of pancreatitis *[see Warnings and Precautions (5.1)]*.

Vital Signs
No clinically meaningful changes in vital signs were observed in patients treated with TRADJENTA.

6.2 Postmarketing Experience
Additional adverse reactions have been identified during postapproval use of TRADJENTA. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Acute pancreatitis, including fatal pancreatitis *[see Indications and Usage (1)]*
- Hypersensitivity reactions including anaphylaxis, angioedema, and exfoliative skin conditions
- Severe and disabling arthralgia
- Bullous pemphigoid
- Rash
- Mouth ulceration, stomatitis
- Rhabdomyolysis

7 DRUG INTERACTIONS
7.1 Inducers of P-glycoprotein or CYP3A4 Enzymes
Rifampin decreased linagliptin exposure, suggesting that the efficacy of TRADJENTA may be reduced when administered in combination with a strong P-gp or CYP3A4 inducer. Therefore, use of alternative treatments is strongly recommended when linagliptin is to be administered with a strong P-gp or CYP3A4 inducer *[see Clinical Pharmacology (12.3)]*.

7.2 Insulin Secretagogues or Insulin
The risk of hypoglycemia is increased when linagliptin is used in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin. Coadministration of TRADJENTA with an insulin secretagogue (e.g., sulfonylurea) or insulin may require lower doses of the insulin secretagogue or insulin to reduce the risk of hypoglycemia *[see Warnings and Precautions (5.2)]*.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
The limited data with TRADJENTA use in pregnant women are not sufficient to inform of drug-associated risk for major birth defects and miscarriage. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy *[see Clinical Considerations]*.

In animal reproduction studies, no adverse developmental effects were observed when linagliptin was administered to pregnant rats during the period of organogenesis at doses similar to the maximum recommended clinical dose, based on exposure *[see Data]*.

The estimated background risk of major birth defects is 6% to 10% in women with pre-gestational diabetes with a HbA1c >7 and has been reported to be as high as 20% to 25% in women with HbA1c >10. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations
Disease-associated maternal and/or embryo/fetal risk
Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, preeclampsia, spontaneous abortions, preterm delivery, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity.

Data

Animal Data

No adverse developmental outcome was observed when linagliptin was administered to pregnant Wistar Han rats and Himalayan rabbits during the period of organogenesis at doses up to 240 mg/kg/day and 150 mg/kg/day, respectively. These doses represent approximately 943-times (rats) and 1943-times (rabbits) the 5 mg maximum clinical dose, based on exposure. No adverse functional, behavioral, or reproductive outcome was observed in offspring following administration of linagliptin to Wistar Han rats from gestation day 6 to lactation day 21 at a dose 49-times the maximum recommended human dose, based on exposure.

Linagliptin crosses the placenta into the fetus following oral dosing in pregnant rats and rabbits.

8.2 Lactation

Risk Summary

There is no information regarding the presence of linagliptin in human milk, the effects on the breastfed infant, or the effects on milk production. However, linagliptin is present in rat milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TRADJENTA and any potential adverse effects on the breastfed child from TRADJENTA or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of TRADJENTA have not been established in pediatric patients.

8.5 Geriatric Use

In linagliptin studies, 1085 linagliptin-treated patients were 65 years of age and older and 131 patients were 75 years of age and older. In these linagliptin studies, no overall differences in safety or effectiveness of linagliptin were observed between geriatric patients and younger adult patients.

8.6 Renal Impairment

No dose adjustment is recommended for patients with renal impairment *[see Clinical Pharmacology (12.3)]*.

In the TRADJENTA treatment arm of the CARMELINA trial *[see Clinical Studies (14)]*, 2200 (63%) patients had renal impairment (eGFR <60 mL/min/1.73 m^2). Approximately 20% of the population had eGFR ≥45 to <60 mL/min/1.73 m^2, 28% of the population had eGFR ≥30 to <45 mL/min/1.73 m^2 and 15% had eGFR <30 mL/min/1.73 m^2. The overall incidence of adverse reactions were generally similar between the TRADJENTA and placebo treatment arms.

8.7 Hepatic Impairment

No dose adjustment is recommended for patients with hepatic impairment *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

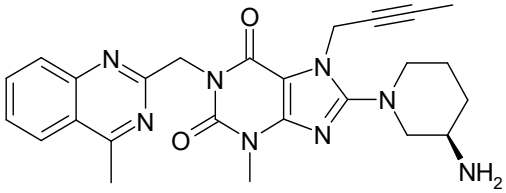
In the event of an overdose with TRADJENTA, contact the Poison Control Center. Removal of linagliptin by hemodialysis or peritoneal dialysis is unlikely.

11 DESCRIPTION

TRADJENTA tablets for oral use contain linagliptin, an inhibitor of the dipeptidyl peptidase-4 (DPP-4) enzyme.

The chemical name of linagliptin is 1H-Purine-2,6-dione, 8-[(3R)-3-amino-1-piperidinyl]-7-(2-butyn-1-yl)-3,7-dihydro-3-methyl-1-[(4-methyl-2-quinazolinyl)methyl]-

The molecular formula is $C_{25}H_{28}N_8O_2$ and the molecular weight is 472.54 g/mol. The structural formula is:



Linagliptin is a white to yellowish, not or only slightly hygroscopic solid substance. It is very slightly soluble in water (0.9 mg/mL). Linagliptin is soluble in methanol (ca. 60 mg/mL), sparingly soluble in ethanol (ca. 10 mg/mL), very slightly soluble in isopropanol (<1 mg/mL), and very slightly soluble in acetone (ca. 1 mg/mL).

Each film-coated tablet of TRADJENTA contains 5 mg of linagliptin free base and the following inactive ingredients: mannitol, pregelatinized starch, corn starch, copovidone, and magnesium stearate. In addition, the film coating contains the following inactive ingredients: hypromellose, titanium dioxide, talc, polyethylene glycol, and red ferric oxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Linagliptin is an inhibitor of DPP-4, an enzyme that degrades the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Thus, linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin in a glucose-dependent manner and decreasing the levels of glucagon in the circulation. Both incretin hormones are involved in the physiological regulation of glucose homeostasis. Incretin hormones are secreted at a low basal level throughout the day and levels rise immediately after meal intake. GLP-1 and GIP increase insulin biosynthesis and secretion from pancreatic beta cells in the presence of normal and elevated blood glucose levels. Furthermore, GLP-1 also reduces glucagon secretion from pancreatic alpha-cells, resulting in a reduction in hepatic glucose output.

12.2 Pharmacodynamics

Linagliptin binds to DPP-4 in a reversible manner and thus increases the concentrations of incretin hormones. Linagliptin glucose-dependently increases insulin secretion and lowers glucagon secretion, thus resulting in better regulation of glucose homeostasis. Linagliptin binds selectively to DPP-4 and selectively inhibits DPP-4, but not DPP-8 or DPP-9 activity *in vitro* at concentrations approximating therapeutic exposures.

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