

Aglip™

Alogliptin Benzoate INN Film Coated Tablet

DESCRIPTION

Aglip™ is Alogliptin preparation which is a dipeptidyl peptidase (DPP)-4 inhibitor thus inhibits DPP-4 and activate GLP-1 to increase insulin production and decrease glucagon secretion. Alogliptin does not decrease the risk of heart attack and stroke. Like other members of the gliptin class, it causes little or no weight gain, exhibits relatively little risk of hypoglycemia, and has relatively modest glucose-lowering activity.

INDICATIONS

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

DOSAGE AND ADMINISTRATION

- Individualize the starting dose of **Aglip™** based on the patient's current regimen with or without food.
- The maximum recommended dose is 25 mg once daily.
- No dose adjustment of Alogliptin is necessary for patients with mild renal impairment (creatinine clearance [CrCl] ≥ 60 mL/min).
- The dose of Alogliptin is 12.5 mg once daily for patients with moderate renal impairment (CrCl ≥ 30 to <60 mL/min).
- The dose of Alogliptin is 6.25 mg once daily for patients with severe renal impairment (CrCl ≥ 15 to <30 mL/min) or with end-stage renal disease (ESRD) (CrCl <15 mL/min or requiring hemodialysis). Alogliptin has not been studied in patients undergoing peritoneal dialysis.

CONTRAINDICATIONS

History of a serious hypersensitivity reaction to alogliptin-containing products, such as anaphylaxis, angioedema or severe cutaneous adverse reactions.

SIDE EFFECTS

- Swelling of face, lips, throat and other areas on your skin
- Difficulty swallowing or breathing
- Skin rash, itching, flaking or peeling
- Nausea or vomiting
- Stomach pain
- Unusual or unexplained tiredness
- Loss of appetite
- Stuffy or runny nose and sore throat
- Headache
- Cold-like symptoms (upper respiratory tract infection)

PRECAUTIONS AND WARNINGS

- Acute pancreatitis: There have been post marketing reports of acute pancreatitis. If pancreatitis is suspected, promptly discontinue Alogliptin.
- Heart failure: Consider the risks and benefits of Alogliptin prior to initiating treatment in patients at risk for heart failure. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuation of Alogliptin.
- Hepatic effects: If liver injury is detected, promptly interrupt Alogliptin and assess patient for probable cause, then treat cause if possible, to resolution or stabilization. Do not restart Alogliptin if liver injury is confirmed and no alternative etiology can be found.
- Hypoglycemia: When an insulin secretagogue (e.g., sulfonylurea) or insulin is used in combination with Alogliptin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia.

To be dispensed only by the prescription of a registered physician.

USE IN PREGNANCY AND LACTATION

Limited data with alogliptin in pregnant women are not sufficient to determine a drug-associated risk for major birth defects or miscarriage. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy.

No adverse developmental effects were observed when alogliptin was administered to pregnant rats and rabbits during organogenesis at exposures 180-and 149-times the 25 mg clinical dose, respectively, based on plasma drug exposure.

There is no information regarding the presence of alogliptin in human milk, the effects on the breastfed infant, or the effects on milk production. Alogliptin is present in rat milk: however, due to species specific differences in lactation physiology, animal lactation data may not reliably predict levels in human milk.

PHARMACEUTICAL PRECAUTION

Store at or below 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Aglip™ 25 Tablet : Box containing 2 strips of 10 tablets each. Each tablet contains Alogliptin Benzoate INN equivalent to Alogliptin 25 mg.

Aglip™ 12.5 Tablet : Box containing 2 strips of 10 tablets each. Each tablet contains Alogliptin Benzoate INN equivalent to Alogliptin 12.5 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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