

Aloglip

Alogliptin Benzoate INN

Composition

Aloglip 6.25 Tablet: Each film coated tablet contains Alogliptin Benzoate INN equivalent to Alogliptin 6.25 mg.

Aloglip 12.5 Tablet: Each film coated tablet contains Alogliptin Benzoate INN equivalent to Alogliptin 12.5 mg.

Aloglip 25 Tablet: Each film coated tablet contains Alogliptin Benzoate INN equivalent to Alogliptin 25 mg.

Pharmacology

Alogliptin is a DPP-4 inhibitor that slows the inactivation of the incretin hormones, thereby increasing their bloodstream concentrations and reducing fasting and postprandial glucose concentrations in a glucose-dependent manner in patients with type 2 diabetes mellitus. Increased concentrations of the incretin hormones such as glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) are released into the bloodstream from the small intestine in response to meals. These hormones cause insulin release from the pancreatic beta cells in a glucose-dependent manner but are inactivated by the DPP-4 enzyme within minutes. GLP-1 also lowers glucagon secretion from pancreatic alpha cells, reducing hepatic glucose production. In patients with type 2 diabetes, concentrations of GLP-1 are reduced but the insulin response to GLP-1 is preserved.

Indication

Aloglip is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type-2 diabetes mellitus.

Dose & Administration

The recommended dose in patients with normal renal function or mild renal impairment is 25 mg once daily **or as directed by the physicians.**

Contraindication

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

Warning & Precaution

Acute pancreatitis: If pancreatitis is suspected, promptly Aloglip should be discontinued.

Hypersensitivity: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with Aloglip such as anaphylaxis, angioedema and severe cutaneous adverse reactions. In such cases, promptly Aloglip should be discontinued.

Hepatic effects: Postmarketing reports of hepatic failure, sometimes fatal. Causality can not be excluded. If liver injury is detected, promptly interrupt Aloglip and assess patient for probable cause, then treat cause if possible, to resolution or stabilization. Do not restart Aloglip 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 Aloglip, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycaemia.

Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Aloglip or any other antidiabetic drug.

Side Effects

Common side effects are nasopharyngitis, headache and upper respiratory tract infection.

Use in Pregnancy & Lactation

Pregnancy: Pregnancy Category B. No adequate or well-controlled studies in pregnant women have been conducted with Aloglip. Aloglip tablets should be used during pregnancy only if clearly needed.

Nursing Mother: It is not known whether alogliptin is excreted in human milk. Caution should be exercised when Aloglip is administered to a nursing woman.

Use in Children & Adolescents

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

Drug Interactions

Aloglip is primarily renally excreted. Cytochrome (CYP) P450-related metabolism is negligible. No significant drug-drug interactions are observed with the CYP-substrates or inhibitors tested or with renally excreted drugs.

Overdose

No serious adverse events were observed.

Storage

Store below 30°C, keep away from light and in a dry place. Keep all medicines out of the reach of children.

Packing

Aloglip 6.25 Tablet: Each box contains 3 X 10 tablets in Alu-Alu blister pack along with an insert.

Aloglip 12.5 Tablet: Each box contains 3 X 10 tablets in Alu-Alu blister pack along with an insert.

Aloglip 25 Tablet: Each box contains 3 X 10 tablets in Alu-Alu blister pack along with an insert.

Manufactured by:

Navana Pharmaceuticals Ltd.

Rupshi, Rupganj, Narayanganj, Bangladesh

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