W=100 mm

Alodia

Tablet

Alogliptin Benzoate INN

Composition

Alodia 25: Each film-coated tablet contains Alogliptin Benzoate INN 34 mg equivalent to 25 mg of Alogliptin.

Alodia 12.5: Each film-coated tablet contains Alogliptin Benzoate INN 17 mg equivalent to 12.5 mg of Alogliptin.

Pharmacology

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 form 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 dipeptidyl peptidase-4 (DPP-4) enzyme tithing 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. 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. Alogliptin selectively binds to and inhibits DPP-4 but not DPP-8 or DPP-9 activity in vitro at concentrations approximating therapeutic exposures.

Indication

Alodia (Alogliptin) 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. It is also indicated for use in combination with Metformin, Sulfonylurea or Pioglitazone when diet and exercise plus the single agent does not provide adequate glycemic control.

Dosage and Administration

Route of administration : Oral.

The recommended dose of **Alodia** (Alogliptin) is 25 mg once daily. **Alodia** can be taken with or without food.

Patients with Renal Impairment

For patients with mild renal impairment, no dosage adjustment for **Alodia** (Alogliptin) is required. For patients with moderate renal impairment, the dose of **Alodia** (Alogliptin) is 12.5 mg once daily. For patients with severe renal impairment or with end-stage renal disease (ESRD), the dose of **Alodia** (Alogliptin) is 6.25 mg once daily.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindication

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

Warning & Precaution

- Should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- If pancreatitis is suspected, **Alodia** should promptly be discontinued and appropriate management should be initiated.
- If a hypersensitivity reaction is suspected, **Alodia** should be promptly discontinued.
- If signs or symptoms of liver injury occur, discontinue **Alodia** and seek medical advice promptly.
- When **Alodia** is used in combination with a sulfonylurea or with insulin, hypoglycemia may occur, a lower dose of sulfonylurea or insulin may be required to reduce the risk of hypoglycemia.

Side Effects

Common side effects : The most common adverse reactions are; allergic reaction; severe rash, hives, swallowing or breathing problems and headache. Hypoglycemia may occur in patients treated with the combination of Alogliptin and sulfonylurea and add-on to insulin.

Rare side effects : The rare adverse reactions are; bullous pemphigoid: blistering of the skin, redness or peeling skin, stevens Johnson syndrome: serious rash, swelling of lips, eyes or mouth & flu like symptoms & liver disorders: unusual or unexplained tiredness loss of appetite.

Use in Pregnancy & Lactation

Pregnant Women: There is no adequate or well-controlled studies in pregnant woman. As a precautionary measure, **Alodia** should not be used during pregnancy.

Nursing Women: It is not known whether **Alodia** is excreted in human milk but a risk to the breast-fed child can not be excluded. **Alodia** should not be used by a woman who is nursing.

Use in Children & Adolescents

The safety and efficacy of **Alodia** in children and adolescents below 18 years have not been established.

Drug Interaction

No significant drug-drug interactions were observed with the CYP-substrate or inhibitors or with renally excreted drugs.

Overdose

If **Alodia** is overdosed no serious adverse reaction were observed but clinical measure should be employed as dictated by patient's clinical status.

Storage

Store below 30^{0}C temperature & dry place, protected from light.

Keep all medicines out of reach of children.

Packing

Alodia 25: Each box contains 3 x 10 tablets in Alu-Alu blister strip.

Alodia 12.5: Each box contains 3 x 10 tablets in Alu-Alu blister strip.

* **Further information is available on request.**

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Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness