

Wikitin

Omarigliptin INN

COMPOSITION

Wikitin 12.5 Tablet: Each film coated tablet contains Omarigliptin INN 12.5 mg.

Wikitin 25 Tablet: Each film coated tablet contains Omarigliptin INN 25 mg.

PHARMACOLOGY

Omarigliptin is a long acting inhibitor of DPP-4, an enzyme that degrades the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Thus, Omarigliptin 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.

INDICATION

Omarigliptin is a once-weekly DPP-4 inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

DOSAGE & ADMINISTRATION

The usual recommended dose of Omarigliptin is 25 mg once weekly as monotherapy or as add-on therapy for optimization of glycemic control. The dosage should be reduced to 12.5 mg once weekly in patients with severe renal dysfunction and in patients with end-stage renal failure or in those requiring hemodialysis or peritoneal dialysis according to the following table:

Renal dysfunction	Serum creatinine values (mg/dL) *eGFR<30	Dose
Severe end-stage kidney failure	Men: Cr>1.9	12.5 mg once a week
	Women: Cr>1.4	

*Conversion value corresponding to the eGFR (60 years of age)

CONTRAINDICATIONS

Patients with a history of hypersensitivity to components of this drug. Severe ketosis, diabetic coma or precoma in type 1 diabetes patients. Severe infection in which glycemic control is desired by insulin injection, before and after surgery. Efficacy and safety of concomitant administration of this drug and insulin preparations have not been studied.

WARNING & PRECAUTIONS

If pancreatitis is suspected, Omarigliptin should promptly be discontinued and appropriate management should be initiated. Dosage adjustment should recommend in patients with moderate or severe renal insufficiency and in patients with ESRD. Assessment of renal function should recommend prior to initiating Omarigliptin. When Omarigliptin is used in combination with a sulfonylurea or with insulin, medications known to cause hypoglycemia, a lower dose of sulfonylurea or insulin may be required to reduce the risk of hypoglycemia. If a hypersensitivity reaction is suspected, Omarigliptin should discontinue.

Following patients or conditions which might cause low blood sugar:

1. Pituitary dysfunction or adrenal insufficiency
2. Malnutrition, starvation, irregular dietary intake, lack of dietary intake or debilitated state
3. Intense muscle movement
4. Excessive alcohol intake
5. The elderly

SIDE EFFECTS

Hypoglycemia, acute pancreatitis, bowel obstruction and intestinal obstruction. Other side effects are: Gastrointestinal problem, constipation, diarrhea, skin and subcutaneous tissue disorders.

ADVERSE REACTIONS

Nasopharyngitis may occur. The adverse effects of Omarigliptin drug were well tolerated.

INTERACTION

Interaction of Omarigliptin is with the following: Metformin, Glimepride, Oral contraceptives, Atorvastatin

USE IN SPECIFIC POPULATIONS

Elderly population: Often renal function is reduced in the elderly patients and this drug is mainly excreted via kidney. Care must be taken especially in patients with severe renal dysfunction, end-stage renal failure patients requiring hemodialysis or peritoneal dialysis. **Children:** Safety and efficacy of this drug in children has not been established. **Pregnant woman:** Clinical trials targeting pregnant women have not been performed so its safety cannot be predicted. Breastfeeding should be avoided.

STORAGE

Store below 30° C, keep in dry place & protect from light. Keep out of reach of children.

PACKING

Wikitin 12.5 Tablet: Each box contains 4's tablets in Alu-Alu blister pack.

Wikitin 25 Tablet: Each box contains 4's tablets in Alu-Alu blister pack.

Manufactured by:

 **ARISTOPHARMA LTD.**
Shampur-Kadamtali I/A, Dhaka-Bangladesh