

# Omarol

## Omarigliptin INN

**Composition : Omarol-12.5 Tablet :** Each film coated tablet contains Omarigliptin INN 12.5mg .

**Omarol-25 Tablet :** Each film coated tablet contains Omarigliptin INN 25mg.

**Pharmacology :** Omarigliptin is a long-acting inhibitor of the enzyme dipeptidyl peptidase-4 (DPP-4).DPP-4 rapidly degrades incretin hormones glucagon-like peptide-1(GLP-1) and glucose-dependent insulintropic polypeptide (GIP).Thus omarigliptin increases the concentrations of active incretin hormones which lower blood glucose concentrations in response to a meal by increasing insulin and decreasing glucagon levels in a glucose-dependent manner .Thus, omarigliptin's mechanism of action (or MOA) augments the action of incretin hormones.

**Indication:** Omarigliptin is a 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 25mg once weekly as monotherapy or as add-on therapy for optimization of glycaemic control. The dosage should be reduced to 12.5mg once weekly in patients with severe renal dysfunction and in patients with end-stage renal failure in those requiring hemodialysis or peritoneal dialysis should be 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 (60years of age). Or as directed by the registered physician.

**Contraindications:** It is contraindicated with the 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.

**Precautions :** Omarigliptin in combination with other anti-diabetic drugs (in particular, insulin preparation or sulfonylurea) should be administered with caution as they might cause hypoglycemia. Some patients or conditions which might cause low blood sugar such as pituitary dysfunction or adrenal insufficiency; malnutrition, starvation, irregular dietary intake, lack of dietary intake or debilitated state; intense muscle movement; excessive alcohol intake and the elderly. Caution should be taken in patients engaged in aerial work or operation of an automobile.

**Side effects :** The adverse effects of Omarigliptin are generally well tolerated. The most common side effects are nasopharyngitis, hypoglycemia, constipation, diarrhea, gastrointestinal problem, skin and subcutaneous tissue disorders.

**Use in Pregnancy and Lactation :** There are no adequate and well controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Breastfeeding should be avoided.

**Use in Child and Elderly Patients:** Safety and efficacy of this drug in children has not been established. 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.

**Drug Interactions:** Interaction of Omarigliptin is with the following: Metformin, Glimepride, Oral contraceptives, Atorvastatin.

**Overdose:** There is no data available.

**Storage:** Store below 30°C. Protect from light and moisture. Keep the medicine out of reach of children.

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

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

Manufactured by



**DRUG INTERNATIONAL LTD.**

Tongi, Gazipur, Bangladesh