

Omarigliptin INN

Composition

**Omari 12.5:** Each film-coated tablet contains Omarigliptin INN 12.5 mg.  
**Omari 25:** Each film-coated tablet contains Omarigliptin INN 25 mg.

Pharmacology

Omari is a long-acting inhibitor of the enzyme dipeptidyl peptidase-4 (DPP-4). DPP-4 rapidly degrades incretin hormones. Incretins lower blood glucose concentrations in response to a meal by increasing insulin and decreasing glucagon levels in a glucose-dependent manner. Thus, Omari's mechanism of action (or MOA) augments the action of incretin hormones.

Indication

Omari is 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 optimisation 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 or in those requiring hemodialysis or peritoneal dialysis according to the following table:

Renal dysfunction	eGFR (ml/min/1.73m <sup>2</sup> ) Serum creatinine values(mg/dL)*eGFR<30	Dose
Severe end-stage kidney failure	Men: Cr>1.9	12.5mg once a week
	Women: Cr>1.4	

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

**Missed dose:** If missed a dose, it is advised to take the missed dose as soon as possible and then follow regular weekly dosing schedule. Patients should never take two doses at one time.  
**Or as directed by the registered physician.**

Contraindication

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, patients with severe trauma, efficacy and safety of concomitant administration of this drug and insulin preparations have not been studied.

Warning & Precaution

Since this drug is mainly excreted by the kidneys therefore dose should be adjusted in patients with severe renal impairment, hemodialysis or peritoneal dialysis and end-stage renal failure. Other anti-diabetic drugs (in particular, insulin preparation or sulfonylurea) should be used with caution in combination with Omarigliptin, as they may cause hypoglycemia. 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

Caution should be taken in patients engaged in aerial work, operation of an automobile. Precaution must be taken with drugs that enhances the hypoglycemic action (β-blockers, salicylic acid agents, monoamine oxidase inhibitors, etc.). Blood glucose level should be carefully monitored when using drugs that attenuate the hypoglycemic action (adrenaline, adrenocorticotrophic hormone, thyroid hormone, etc.).

Side effect

**Common side effects:** Hypoglycemia, acute pancreatitis, bowel obstruction and intestinal obstruction.  
**Rare side effects:** Gastrointestinal problem, constipation, diarrhea, skin and subcutaneous tissues disorders.

Use in Pregnancy & Lactation

Clinical trials targeting pregnant women have not been performed so its safety cannot be predicted. Breastfeeding should be avoided.

Use in Children & Adolescents

The safety of Omari tablets in children has not been established .

Geriatric Use

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

Drug Interaction

Interaction of Omari is with the following:

- Metformin
- Glimepride
- Oral contraceptives
- Atorvastatin

Overdose

Not available

Storage

Store below 30<sup>0</sup> C temperature and dry place, protect from light, Keep all medicines out of reach of children. Do not freeze.

Packing

Each box contains 1 x 4 tablets in Alu-Alu blister Strips and an insert.

\* Further information is available on request.



Manufactured by:  
**The ACME Laboratories Ltd.**  
Dhulivita, Dhamrai, Dhaka, Bangladesh  
For Health, Vigour and Happiness