

# Emfolin

## Empagliflozin & Linagliptin Tablet

### Presentation

**Emfolin 10/5 Tablet:** Each tablet contains Empagliflozin INN 10 mg and Linagliptin INN 5 mg

**Emfolin 25/5 Tablet:** Each tablet contains Empagliflozin INN 25 mg and Linagliptin INN 5 mg

### Indications

Emfolin is indicated for using as an adjunct to diet and exercise, to control the glycemic level in adult patients with type 2 diabetes mellitus (T2DM) who are:

- Inadequately controlled on Metformin and Empagliflozin, or
- Inadequately controlled on Metformin and Linagliptin or
- Already controlled with the free combination of Metformin, Empagliflozin and Linagliptin.

### Dosage & Administration

The recommended dose of Empagliflozin and Linagliptin 10/5 and 25/5 mg, can be taken once with or without food and at any time of day, preferably at the same time of the day.

### Recommended Starting Dose

For patients with T2DM inadequately controlled on:

- Metformin and Linagliptin 5 mg, the recommended dose of Emfolin is Empagliflozin 10 mg/Linagliptin 5 mg, once daily.
- Metformin and Empagliflozin 10 mg, the recommended dose of Emfolin is Empagliflozin 10 mg/Linagliptin 5 mg, once daily.
- Metformin and Empagliflozin 25 mg, the recommended dose of Emfolin is Empagliflozin 25 mg/Linagliptin 5 mg, once daily.

### Hepatic Impairment:

No dosage adjustment for Emfolin is necessary for patients with mild or moderate hepatic impairment.

### Side Effects

The most common adverse reactions associated with Emfolin are urinary tract infection, nasopharyngitis, upper respiratory tract infection, gastroenteritis and bronchitis. The most common (>1%) treatment-related adverse events were urinary tract infection and lipase increased.

### Precautions

Emfolin should not be used for the treatment of diabetes ketoacidosis (DKA) or in patients with a history of DKA. Emfolin should not be used in patients who are ECF (Extracellular Fluid) volume-depleted. It causes diuresis that may be associated with decreases in blood pressure. It should not initiate in patients with an eGFR less than 45 mL/min/1.73m<sup>2</sup>.

### Contraindications

Emfolin is contraindicated in patients with:

- A history of a hypersensitivity reaction to Emfolin, its active substances, its excipients or to any dipeptidyl peptidase 4 (DPP-4) inhibitor or sodium-glucose co-transporter 2 (SGLT2) inhibitor;
- Renal impairment with an estimated glomerular filtration rate (eGFR) less than 45 mL/min/1.73 m<sup>2</sup> or on dialysis;
- Diabetic ketoacidosis (DKA);
- Type 1 diabetes mellitus

### Overdose

If you think there has been an overdose, contact with your nearby healthcare center.

### Drug Interactions

**Rifampicin:** Co-administration of Linagliptin with Rifampicin decreased the C<sub>max</sub> and AUC of Linagliptin by 43.8% and 39.6%, respectively.

**Inducers of P-gp (P-Glycoprotein) or CYP3A4 isozymes:** The co-administration of Linagliptin and potent inducers of P-gp and CYP3A4, other than Rifampicin (such as carbamazepine, dexamethasone, phenobarbital and phenytoin) have not been studied but may result in a decreased plasma concentration of Linagliptin and an increased concentration of its major metabolite. Therefore, glycemic control should be carefully assessed when Emfolin is used concomitantly with a potent P-gp/CYP3A4 inducer.

**UGT inducers:** Empagliflozin is primarily metabolized via uridine 5'-diphosphoglucuronosyltransferases (UGT). The effect of UGT induction on Empagliflozin has not been studied. Nevertheless, co-medication with known inducers of UGT enzymes should be avoided because of risk of decreased efficacy of Emfolin.

### Use in Pregnancy & Lactation

During pregnancy, Emfolin should be taken only if prescribed by doctor. It is unknown if Empagliflozin & Linagliptin pass into breast milk. Consult doctor before breastfeeding.

### Storage

Store below 30°C and dry place, away from light. Keep out of the reach of children.

### Packing

**Emfolin 10/5 Tablet:** Each box contains 3 blister packs with each blister of 10 tablets.

**Emfolin 25/5 Tablet:** Each box contains 3 blister packs with each blister of 10 tablets.

Manufactured by:

 **GENERAL**  
Pharmaceuticals Ltd.  
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