

# Sinjard-L

Empagliflozin INN & Linagliptin INN

## COMPOSITION

**Sinjard-L 10 Tablet:** Each film coated tablet contains Empagliflozin INN 10 mg and Linagliptin INN 5 mg.

**Sinjard-L 25 Tablet:** Each film coated tablet contains Empagliflozin INN 25 mg and Linagliptin INN 5 mg.

## PHARMACOLOGY

**Sinjard-L** combines two antihyperglycemic agents with complementary mechanisms of action to improve glycemic control in patients with type 2 diabetes mellitus: Empagliflozin, a Sodium-glucose co-transporter-2 (SGLT-2) inhibitor and Linagliptin, an inhibitor of dipeptidyl peptidase-4 (DPP-4).

Sodium-glucose co-transporter-2 (SGLT2) expressed in the proximal renal tubules, is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. By inhibiting SGLT2, Empagliflozin reduces reabsorption of filtered glucose and lowers the Renal Threshold for Glucose (RTG), and thereby increases urinary glucose excretion.

Dipeptidyl peptidase-4 (DPP-4), an enzyme that degrades the incretin hormones GLP-1 (glucagon like peptide-1) and GIP (glucose dependent insulinotropic polypeptide). Thus, Linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin from pancreatic beta ( $\beta$ ) cells in a glucose-dependent manner and decreasing the secretion of glucagon from pancreatic alpha ( $\alpha$ ) cells in the circulation.

## INDICATION

**Sinjard-L** is indicated as an adjunct to Metformin along with diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Empagliflozin and Linagliptin is appropriate. **Sinjard-L** can be used:

- in patients who are not controlled with Empagliflozin and Metformin, or
- in patients who are not controlled with Empagliflozin and Metformin, or
- in patients currently taking Metformin, Empagliflozin and Linagliptin as separate tablets.

## DOSAGE AND ADMINISTRATION

**Sinjard-L** comes in two strengths: 10 mg/5 mg tablets and 25 mg/5 mg tablets. Individualize the starting dose based on the patient's current regimen. **Sinjard-L** should be taken as one tablet once a day with or without food. Follow the directions given by doctor.

## MISSED DOSE

- If it is 12 hours or more until next dose, take **Sinjard-L** as soon as remember. Then take next dose at the usual time.
- If it is less than 12 hours until next dose, skip the missed dose & take next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

## OVERDOSE

In the event of an overdose with Sinjard-L, employ the usual supportive measures (e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment) as dictated by the patient's clinical status even if there are no symptoms.

## SIDE EFFECTS

*For Empagliflozin:*

The most common adverse reactions associated with Empagliflozin are urinary tract infections and female genital mycotic infections. Other common side effects include dehydration, hypotension, weakness, dizziness and increased thirstiness.

*For Linagliptin:*

Most common side effects are nasopharyngitis and diarrhea.

Hypoglycemia is more common in patients treated in combination with Metformin and Sulfonylureas.

## SERIOUS WARNINGS AND PRECAUTIONS

Diabetic ketoacidosis (DKA) is a serious and life-threatening condition that requires urgent hospitalization. DKA has been reported in patients with type 2 diabetes with normal or high blood sugar levels who are treated with empagliflozin (one of the medicines in Sinjard-L. Some cases of DKA have led to death.

Seek medical attention right away and stop taking **Sinjard-L** immediately if you have any of the following symptoms (even if your blood sugar levels are normal): difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusually tired or sleepy, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat.

Do not use **Sinjard-L** if you are:

- are allergic to any of the ingredients in Sinjard-L including Empagliflozin (or any other SGLT2 inhibitor) and Linagliptin (or any other DPP-4 inhibitor);
- have severe kidney problems or are on dialysis;
- have severe liver disease;
- have DKA or a history of DKA;
- have type 1 diabetes;
- are experiencing loss of fluids from the body due to vomiting, diarrhea or dehydration;
- are under 18 years of age.

## DRUG INTERACTION

The following may interact with Sinjard-L:

- some medicines, including Insulin, that are used to treat diabetes;
- medicines used to treat seizures such as Phenobarbital, Carbamazepine and Phenytoin;
- Rifampin (used to treat bacterial infections), Dexamethasone (a steroid);
- medicines to lower your blood pressure;
- diuretics, known as water pills, such as furosemide. They are used to remove excess water from the body;

## PREGNANCY AND LACTATION

Pregnancy: There are no adequate and well-controlled studies of Empagliflozin & Linagliptin combination in pregnant women. **Sinjard-L** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: **Sinjard-L** is not recommended when breastfeeding.

## STORAGE CONDITION

Store below 30°C and dry place, away from light. Store in the original package in order to protect from moisture. Keep out of the reach of children.

## COMMERCIAL PACK

**Sinjard-L 10 Tablet:** Each commercial box contains 28 film coated tablets in Alu-Alu blister.

**Sinjard-L 25 Tablet:** Each commercial box contains 14 film coated tablets in Alu-Alu blister.

Manufactured By  
**BEACON**<sup>®</sup>  
Pharmaceuticals Limited  
Bhaluka, Mymensingh, Bangladesh