

Composition: Emparol 10 : Each film coated tablet contains Empagliflozin INN 10mg.

Emparol 25 : Each film coated tablet contains Empagliflozin INN 25mg.

Indication: It is indicated

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and

- to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Dosage and Administration : The recommended dose is 10mg once daily, taken in the morning, with or without food. In patients tolerating Empagliflozin, the dose may be increased to 25mg once daily. In patients with volume depletion, correcting this condition prior to initiation of Empagliflozin is recommended. Or, as directed by the registered physician.

Side Effect : The most common adverse reactions associated with Empagliflozin are urinary tract infections and female genital mycotic infections. Others common side effects includes: dehydration, hypotension, weakness, dizziness and increased thirstiness.

Precaution : Assessment of renal function is recommended prior to initiation of Empagliflozin and periodically thereafter. Empagliflozin should not be initiated in patients with an eGFR less than 45 mL/min/1.73m². No dose adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m².

Contraindication : Empagliflozin is contraindicated in patients with history of serious hypersensitivity reaction to Empagliflozin or any of its ingredients, severe renal impairment, end-stage renal disease, or dialysis.

Drug Interaction : Diuretics: Co-administration of Empagliflozin with diuretics resulted in increased urine volume.

Insulin or Insulin Secretagogues: Co-administration of Empagliflozin with Insulin or Insulin secretagogues increases the risk for hypoglycemia.

Positive Urine Glucose Test: Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT-2 inhibitors as SGLT-2 inhibitors increase urinary

Emparol

Empagliflozin INN 10mg & 25mg Tablet



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glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control. **Interference with 1,5-anhydroglucitol (1,5-AG) Assay:** Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT-2 inhibitors. Use alternative methods to monitor glycemic control.

Use in Pregnancy and lactation: There are no adequate and well controlled studies of Empagliflozin in pregnant women. Empagliflozin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if Empagliflozin is excreted in human milk. It is not recommended when breastfeeding.

Storage: Keep all medicine out of reach of children. Store below 30^o C in a dry place.

Packing: Emparol 10 : Each box contains 1 x 14's tablets in blister pack.

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