Film-coated tablets containing 10 mg or 25 mg empagliflozin. Indication: Type 2 diabetes mellitus: Jardiance is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: as monotherapy when metformin is considered inappropriate due to intolerance; in addition to other medicinal products for the treatment of diabetes. For study results with respect to combinations, effects on glycemic control and cardiovascular events, and the populations studied, refer to the Summary of Product Characteristics. Heart failure: Jardiance is indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction. Dose and Administration: Type 2 diabetes mellitus: The recommended starting dose is 10 mg once daily. In patients tolerating empagliflozin 10 mg once daily who have eGFR <80 ml/min/1.73 m² and need tighter glycemic control, the dose can be increased to 25 mg once daily. The maximum daily dose is 25 mg. Renal impairment: The glycemic efficacy of empagliflozin is dependent on renal function. Empagliflozin should not be initiated in patients with an eGFR <60 ml/min/1.73 m² or CrCl <60 ml/min. In patients tolerating empagliflozin whose eGFR falls persistently below 60 ml/min/1.73 m² or CrCl below 60 ml/min, the dose of empagliflozin should be adjusted to or maintained at 10 mg once daily. Empagliflozin should be discontinued when eGFR is persistently below 45 ml/min/1.73 m² or CrCl persistently below 45 ml/min. No dose adjustment is required for patients with an eGFR ≥60 ml/min/1.73 m² or CrCl ≥60 ml/min.

Warnings and Precautions: Risk for volume depletion: Should be taken into account. In patients aged 85 years and older, initiation of empagliflozin therapy is not recommended due to the limited therapeutic experience. Elderly patients: No dose adjustment is recommended based on age. In patients 75 years and older, an increased risk for volume depletion should be taken into account. In patients aged 85 years and older, initiation of empagliflozin therapy is not recommended due to the limited therapeutic experience. Renal impairment: Jardiance is not recommended when the calculated glomerular filtration rate (GFR) is persistently below 45 ml/min/1.73 m² or CrCl <60 ml/min. In patients tolerating empagliflozin whose eGFR is persistently below 60 ml/min/1.73 m² or CrCl <60 ml/min, the dose of empagliflozin should be adjusted to or maintained at 10 mg once daily. Empagliflozin should be discontinued when eGFR is persistently below 45 ml/min/1.73 m² or CrCl persistently below 45 ml/min. No dose adjustment is required for patients with an eGFR ≥60 ml/min/1.73 m² or CrCl ≥60 ml/min.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).