For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.
Warning: To be sold by retailer under prescription of Nephrologist/Cardiologist/Consultant Physician/Diabetologist only.

ABBREVIATED PRESCRIBING INFORMATION (API)

Kerendia™ 10/20. Composition: Each film-coated tablet contains 10 mg or 20 mg Finerenone micronized. **Indication [1] CKD T2D:** Finerenone is indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). **Indication [2] Heart Failure (LVEF ≥40%):** Finerenone is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥40%. **Administration**: Initiation of Kerendia treatment is recommended when serum potassium ≤ 4.8 mmol/L. If serum potassium > 4.8 to 5.0 mmol/L, initiation of Kerendia treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on patient characteristics and serum potassium levels and not recommended if serum potassium > 5.0 mmol/L. In patients with heart failure (LVEF ≥40%), initiation of Kerendia treatment is recommended when serum potassium ≤5.0 mmol/L. Measure estimated glomerular filtration rate (eGFR) to determine the starting dose. **Dosage:** The starting dose of Kerendia is 20 mg once daily if eGFR ≥ 60 mL/min/1.73 m2 and 10 mg once daily if eGFR ≥ 25 to < 60 mL/min/1.73 m2 For patients with CKD T2D, the recommended target dose of Kerendia is 20 mg once daily. For patients with heart failure (LVEF ≥40%), the recommended target dose of Kerendia, 40 mg once daily if eGFR ≥60 mL/min/1.73m2 and 20 mg once daily if eGFR ≥25 to <60 mL/min/1.73m2. Tablets should not be taken with grapefruit or grapefruit juice. **Elderly:** No dose adjustment is necessary in elderly patients. **Renal impairment:** Initiation of treatment: In patients with eGFR < 25 mL/min/1.73 m2, finerenone treatment should not be initiated due to limited clinical data. In patients with eGFR < 15 mL/min/1.73 m2, finerenone treatment can be continued caution regarding serum potassium levels as clinical experience is limited. **Contraindication:** Concomitant treatment with strong CYP3A4 inhibitors; patients with Addison's disease. **Warnings & precautions:** Hyperkalaemia has been observed in patients treated with finerenone. Risk factors to develop hyperkalaemia include low eGFR, higher serum potassium and previous episodes of hyperkalaemia. In these patients more frequent monitoring has to be considered. Finerenone treatment should not be initiated in patients with serum potassium >5.0 mmol/L, with eGFR < 25 mL/min/1.73 m2, or severe hepatic impairment. Withhold finerenone treatment if serum potassium is >5.5 mmol/L in patients with CKD T2D, and if serum potassium ≥6.0 mmol/L in patients with HF with LVEF ≥40%. **Special populations:** Pregnant & lactation women, pediatric patient safety not proved. No data is available. **Undesirable effects:** Very common: hyperkalaemia. Common: hyponatraemia, hyperuricemia, hypotension, blood creatinine increased, glomerular filtration rate decreased. Prescribers should consult the full product insert in relation to other side effects. **Overdose:** The most likely manifestation of overdose is anticipated to be hyperkalaemia. If hyperkalaemia develops, standard treatment should be initiated. Finerenone is unlikely to be efficiently removed by haemodialysis given its fraction bound to plasma proteins of about 90%. For further prescribing information, please contact Bayer Pharma Private Limited, Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra, India Pin-400607. Email: medicalinfo.india@bayer.com. Source: PI version: KE_2025_01 dated July 2025. Based on CCDS v2.0 / 29 Oct 2021; CCDS v03 / 15 Dec 2021. Rev Oct 2022; CCDS v04/20 Dec 2024 and US indication statement for CKD T2D approved dated 09-Jul-2021 and HF approved dated 11-Jul-2025. Date of preparation of API, May 2022; 2nd revision dated Oct 2022; 3rd revision dated Nov 2025.

Adverse events should be reported to email: drugsafety.mumbai@bayer.com / at https://safetrack-public.bayer.com/