**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

**Kerendia™ 10/20. Composition**: Each film-coated tablet contains 10 mg or 20 mg Finerenone micronized. **Indication:** 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). **Dosage & administration**: The recommended target dose of Kerendia is 20 mg once daily. 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. Measure estimated glomerular filtration rate (eGFR) to determine the starting dose. 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 and is not recommended in patients with eGFR < 25 mL/min/1.73 m2 as clinical experience is limited. 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 with dose adjustment based on serum potassium. **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. If serum potassium >5.5 mmol/L, finerenone treatment has to be withheld. **Special populations:** Pregnant & lactation women, pediaric patients safety not proved. No data are available. **Undesirable effects:** Very common: hyperkalaemia. Common: hyponatraemia, hyperuricemia, hypotension, 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 Zydus Pharma Private Limited, Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra, India Pin-400607. Email: medicalinfo.india@bayerzyduspharma.com. Source: PI version: KE_2022_02 dated Oct 2022. Based on CCDS v2.0 / 29 Oct 2021; CCDS v03 / 15 Dec 2021. Rev Oct 2022. Date of preparation of API, May 2022; 2nd revision dated Oct 2022.

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