Finora™
(Finerenone)
Tablet

فینورا

COMPOSITION:
Finora Tablet 10 mg:
Each film coated tablet contains:
Finerenone ..... 10 mg.

Product Specs.: Innovator

Finora Tablet 20 mg:
Each film coated tablet contains:
Finerenone ..... 20 mg.

Product Specs.: Innovator

INDICATIONS: Finerenone is indicated for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.

POSOLOGY:
The recommended target dose is 20 mg finerenone once daily.
The maximum recommended dose is 20 mg finerenone once daily.
Initiation of treatment: Serum potassium and estimated glomerular filtration rate (eGFR) have to be measured to determine if finerenone treatment can be initiated and to determine the starting dose.
If serum potassium ≤ 4.8 mmol/L, finerenone treatment can be initiated. For monitoring of serum potassium, see below 'Continuation of treatment.'
If serum potassium > 4.8 to 5.0 mmol/L, initiation of finerenone treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on patient characteristics and serum potassium levels.
If serum potassium > 5.0 mmol/L, finerenone treatment should not be initiated.
The recommended starting dose of finerenone is based on eGFR and is presented in table 1.
Table 1: Initiation of finerenone treatment and recommended dose

eGFR (mL/min/1.73 m^2)	Starting dose (once daily)
≥ 60	20 mg
≥ 25 to < 60	10 mg
< 25	Not recommended

Continuation of treatment:
Serum potassium and eGFR have to be remeasured 4 weeks after initiation or re-start of finerenone treatment or increase in dose (see table 2 to determine continuation of finerenone treatment and dose adjustment).
Thereafter, serum potassium has to be remeasured periodically and as needed based on patient characteristics and serum potassium levels.
Table 2: Continuation of finerenone treatment and dose adjustment

		Current finerenone dose (once daily)	
		10 mg	20 mg
Current serum potassium (mmol/L)	≤ 4.8	Increase to 20 mg finerenone once daily*	Maintain 20 mg once daily
	> 4.8 to 5.5	Maintain 10 mg once daily	Maintain 20 mg once daily
	> 5.5	Withhold finerenone. Consider re-starting at 10 mg once daily when serum potassium ≤ 5.0 mmol/L.	Withhold finerenone. Re-start at 10 mg once daily when serum potassium ≤ 5.0 mmol/L.

* maintain 10 mg once daily, if eGFR has decreased > 30% compared to the previous measurement.

Missed dose: A missed dose should be taken as soon as the patient notices, but only on the same day. The patient should not take 2 doses to make up for a missed dose.

SPECIAL POPULATIONS:
- ***Elderly:*** No dose adjustment required.
- ***Renal Impairment:***
  - Do not initiate if eGFR < 25 mL/min/1.73 m².
  - Continue treatment if eGFR ≥ 15 mL/min/1.73 m², adjusting dose based on serum potassium.
  - Recheck eGFR after 4 weeks to determine dose increase to 20 mg.
  - Discontinue if eGFR < 15 mL/min/1.73 m² (end-stage renal disease).
- ***Hepatic Impairment:***
  - **Severe:** Do not initiate (no data).
  - **Moderate:** No initial dose change; monitor potassium more closely.
  - **Mild:** No dose adjustment needed.
- ***Concomitant Medications:*** When used with moderate/weak CYP3A4 inhibitors, potassium supplements, or trimethoprim (±sulfamethoxazole), monitor serum potassium more frequently; temporary discontinuation may be required.
- ***Body Weight:*** No adjustment needed.
- ***Paediatric Population:*** Safety and efficacy not established in patients <18 years.

METHOD OF ADMINISTRATION:
Oral use:
- Tablets may be taken with a glass of water and with or without food.
- Tablets should not be taken with grapefruit or grapefruit juice.

Crushing of tablets: For patients who are unable to swallow whole tablets, tablets may be crushed and mixed with water or soft foods, such as apple sauce, directly before oral use.

CONTRAINDICATIONS:
- Hypersensitivity to the active substance or to any of the excipients.
- Addison's disease

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
- ***Hyperkalaemia:*** Finerenone may cause hyperkalaemia, especially in patients with low eGFR, elevated baseline potassium, or prior hyperkalaemia. Such patients require closer monitoring.
- ***Treatment Initiation & Continuation:***
  - Do not start if serum K^+ > 5.0 mmol/L.
  - If K^+ 4.8–5.0 mmol/L, initiate with close monitoring within 4 weeks.
  - If K^+ > 5.5 mmol/L, withhold treatment and follow local hyperkalaemia management.
  - Restart at 10 mg once daily when K^+ ≤ 5.0 mmol/L.
- ***Monitoring:*** Check serum potassium and eGFR 4 weeks after start, restart, or dose increase; then monitor periodically as needed.

CONCOMITANT MEDICATIONS:
Avoid use with:
  - Potassium-sparing diuretics (e.g., amiloride, triamterene)
  - Other MRAs (e.g., eplerenone, spironolactone)
  - Use with caution and monitor K^+ when combined with potassium supplements, trimethoprim, or trimethoprim/sulfamethoxazole (temporary discontinuation may be needed).
- ***Renal Impairment:*** Do not initiate if eGFR < 25 mL/min/1.73 m². Discontinue if eGFR falls below 15 mL/min/1.73 m² (end-stage renal disease).
- ***Hepatic Impairment:*** Avoid use in severe hepatic impairment; use cautiously in moderate impairment with additional potassium monitoring.
- ***Heart Failure:*** Not studied in patients with HFrEF (NYHA II–IV).

DRUG INTERACTIONS:
- ***Strong CYP3A4 Inhibitors:*** Contraindicated with itraconazole, clarithromycin, ketoconazole, ritonavir, nelfinavir, cobicistat, telithromycin, or nefazodone due to marked increase in finerenone exposure.
- ***CYP3A4 Inducers (Strong/Moderate):*** Avoid use with rifampicin, carbamazepine, phenytoin, phenobarbital, St. John's Wort, efavirenz, and similar agents as they reduce finerenone levels and efficacy.
- ***Drugs Increasing Serum Potassium:*** Avoid with potassium-sparing diuretics (e.g., amiloride, triamterene) or other MRAs (e.g., eplerenone, spironolactone) due to hyperkalaemia risk.
- ***Grapefruit:*** Avoid grapefruit or its juice; inhibits CYP3A4 and increases finerenone exposure.
- ***Moderate CYP3A4 Inhibitors:*** Erythromycin and verapamil increase finerenone AUC (≈2–3.5×). Monitor serum potassium, especially during initiation or dose changes.
- ***Weak CYP3A4 Inhibitors:*** Fluvoxamine increases AUC (~1.6×); monitor serum potassium accordingly.
- ***Other Potassium-Increasing Drugs:*** Caution with potassium supplements or trimethoprim (±sulfamethoxazole); monitor potassium and consider temporary finerenone discontinuation.
- ***Antihypertensives:*** Concomitant use may raise hypotension risk; monitor blood pressure.

FERTILITY, PREGNANCY & LACTATION:
Contraception in females: Women of childbearing potential should use effective contraception during finerenone treatment.
Pregnancy: There are no data from the use of finerenone in pregnant women. Studies in animals have shown reproductive toxicity. Finerenone should not be used during pregnancy unless the clinical condition of the woman requires treatment with finerenone. If the woman becomes pregnant while taking finerenone, she should be informed of potential risks to the foetus.
Breast-feeding: It is unknown whether finerenone/metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Finerenone therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Fertility: There are no data on the effect of finerenone on human fertility. Animal studies have shown impaired female fertility at exposures considered in excess to the maximum human exposure, indicating low clinical relevance.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
Finerenone has no influence on the ability to drive and use machines.

ADVERSE EFFECTS:
The most frequently reported adverse reaction under treatment with finerenone was hyperkalaemia (14.0%).
Adverse reactions are grouped according to their frequencies in the order of decreasing seriousness. Frequencies are defined, as follows: Very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).
Table 3: Adverse reactions.

System Organ Class (MedDRA)	Very common	Common	Common
Metabolism and nutrition disorders	Hyperkalaemia	Hyponatraemia Hyperuricaemia	
Vascular disorders		Hypotension	
Skin and subcutaneous tissue disorders		Pruritus	
Investigations		Glomerular filtration rate decreased	Haemoglobin decreased

PHARMACOLOGICAL PROPERTIES:
Pharmacotherapeutic group: diuretics, aldosterone antagonists, **ATC code:** C03DA05
Mechanism of action:
Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR) which is activated by aldosterone and cortisol and regulates gene transcription. Its binding to the MR leads to a specific receptor-ligand complex that blocks recruitment of transcriptional coactivators implicated in the expression of pro-inflammatory and pro-fibrotic mediators.

PHARMACOKINETIC PROPERTIES:
Absorption: Finerenone is rapidly and almost completely absorbed after oral intake, reaching peak plasma levels in 0.5–1.25 hours (bioavailability ~43.5%). P-glycoprotein has minimal impact on its absorption.
It may be taken with or without food.
Distribution: Steady-state volume of distribution is 52.6 L. Finerenone is ~92% bound to plasma proteins, mainly albumin.
Metabolism: Metabolized primarily by CYP3A4 (≈90%) and CYP2C8 (≈10%) into inactive metabolites.
Elimination: Half-life is 2–3 hours; clearance ~25 L/h. About 80% of the dose is excreted in urine and 20% in feces, mainly as metabolites (<1% unchanged).

OVERDOSE:
The most likely manifestation of overdose is anticipated to be hyperkalaemia. If hyperkalaemia develops, standard treatment should be initiated. It is unlikely to be efficiently removed by haemodialysis given its fraction bound to plasma proteins of about 90%.

INSTRUCTIONS:
This medicinal product does not require any special storage conditions.
– Store below 30ºC.
– Protect from heat, sunlight & moisture.
– Keep out of the reach of children.
– To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Finota Tablet 10 mg : Pack of 2 x 10 tablets.
Finota Tablet 20 mg : Pack of 2 x 10 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATIONS PLEASE CONTACT:

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