Finerenone

10mg - 20mg

Film-Coated Tablet

Therapeutic Class:

Diuretics, Aldosterone Antagonists

Therapeutic Indication:

- Finerenone is indicated for the treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults[1,2].
- this medicine 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)[3].
- Finerenone works by blocking the action of certain hormones (mineralocorticoids) that can damage your kidneys and heart[1,2].

➢ **Keep this leaflet. You may need to read it again**
For further information, please contact:
Phone: +98-21-88020579 or +98-21-40882675
Website: www.ozhanpharm.com
Email: info@ozhanpharm.com

General Information For The patient:

This medicine has been prescribed specifically for the treatment of your current illness, therefore, do not pass it on to others.
Talk to your physician or pharmacist if any of the following applies to you:
1. A history of allergy.
2. Pregnancy or breastfeeding.
3. Underlying conditions such as Addison's disease.
4. Concomitant use of other medicines, potassium supplements, or dietary salts containing potassium.

Contraindications:

Do not take Finerenone under the following conditions, and talk to your physician or pharmacist:
- If you are allergic to Finerenone or any of the other ingredients of this medicine[1].
- If you are taking itraconazole or ketoconazole, ritonavir, nelfinavir, cobicistat, clarithromycin or nefazodone[1].
- If you have Addison's disease (when your body does not produce enough of the hormones 'cortisol' and 'aldosterone')[1].

Pregnancy and Breastfeeding:

Finerenone should not be used during pregnancy unless your doctor states it is clearly necessary.
You should not breast-feed while taking this medicine[1].

Warnings:

Talk to your physician or pharmacist before taking Finerenone. Your physician may test your blood to check your potassium level and how your kidneys are working.
- Do not give this medicine to children and adolescents under 18 years because it is not known yet whether it is safe and effective in this age group[1].
- If you have a high level of potassium in your blood (hyperkalaemia), serum potassium > 5.0 mmol/L, Finerenone treatment should not be initiated[1].
- If you have severe kidney failure (eGFR< 25 mL/min/1.73 m²) Finerenone treatment should not be initiated.
- If you have moderate or severe liver problems[1].
- If you have mild, moderate or severe heart failure[1].

Precautions:

- This medicine has no effect on your ability to drive or use machines[1].
- If you miss a day to take Finerenone , take the next tablet on the next day. Do not take 2 tablets to make up for a forgotten tablet[1].

Drug Interactions:

Talk to your physician or pharmacist if you are taking any other medicines. Key interactions include:
- **Concomitant use contraindicated:**
  - Concomitant use of Finerenone with itraconazole, ketoconazole, clarithromycin, telithromycin, ritonavir, nelfinavir, cobicistat, or nefazodone is contraindicated, since a marked increase in Finerenone exposure is expected[1].
- **Concomitant use not recommended:**
  - Finerenone should not be used concomitantly with rifampicin, carbamazepine, phenytoin, phenobarbital, (St. John's Wort) or with efavirenz. These medicines are expected to markedly decrease Finerenone plasma concentration and result in reduced therapeutic effect[1].
  - Finerenone should not be used concomitantly with amiloride, triamterene, eplerenone, esaxerenone, spironolactone, canrenone. As these medicinal products increase the risk for hyperkalaemia[1].
  - Grapefruit or grapefruit juice should not be consumed during Finerenone treatment, as it is expected to increase the plasma concentrations of Finerenone[1].
- **Concomitant use with precautions:**
  - Concomitant use of erythromycin (500 mg three times a day), verapamil (240 mg controlled-release tablet once daily) or fluvoxamine (100 mg twice daily) increase Finerenone concentration in the blood and serum potassium may increase; therefore, monitoring of serum potassium is recommended[1].
- Concomitant use of Finerenone with potassium supplements and trimethoprim, or trimethoprim/sulfamethoxazole is anticipated to increase the risk of hyperkalaemia. Monitoring of serum potassium is required[1].
- The risk for hypotension increases with concomitant use of Finerenone with multiple other antihypertensive medicinal products. In these patients, blood pressure monitoring is recommended[1].

Dosage and Administration:

Adults:
- The recommended target dose and the maximum daily dose of this medicine is 1 tablet of 20 mg. Always take 1 tablet (10 mg or 20 mg) once daily[1].
- If serum potassium > 5.0 mmol/L, Finerenone treatment should not be initiated[1].
- In patients with eGFR < 25 mL/min/1.73 m^2, Finerenone treatment should not be initiated due to limited clinical data[1].
- No dose adjustment is necessary in elderly patients[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

- 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)[1].

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

- You can take the tablet with a glass of water with or without food.
- If you cannot swallow the tablet whole, you can crush it, mix it with water or soft foods.

Side Effects:

Like all medicines, this medicine can cause side effects, although not everybody gets them. If any of the side effects listed below become severe, tell your physician or pharmacist.
Side effects that your Physician may see in your blood test results:
- very common:
  - high potassium level (hyperkalaemia), Possible signs of high potassium level in the blood may include weakness or tiredness, feeling sick (nausea), numbness in the hands and lips, muscle cramps, decreased pulse rate[1].
- common:
  - low sodium level (hyponatraemia), Possible signs of low sodium level in the blood may include feeling sick (nausea), tiredness, headache, confusion; muscle weakness, spasms or cramps[1].
  - decrease in how well the kidneys filter blood (glomerular filtration rate decreased).
  - high uric acid level (hyperuricaemia)[1].
- uncommon:
  - decrease in a protein (haemoglobin) in red blood cells[1].

Other side effects:
- Common:
  - low blood pressure (hypotension), Possible signs of low blood pressure may include dizziness, lightheadedness, fainting[1].
  - itching (pruritus)[1].

Overdose:

In case of accidental overdose, immediately seek medical attention or contact a healthcare provider[1].

Storage Instructions:

- Store the medicine at temperatures below 30°C, away from light and moisture.
- Keep this medicine out of the sight and reach of children[1].

Packaging and Available Strengths:

➢ **10 mg film-coated tablets:**
Each film-coated tablet contains 10 mg of Finerenone / 30 tablets per bottle or 3 blisters of 10 tablets, both in a cardboard box with a leaflet.

➢ **20 mg film-coated tablets:**
Each film-coated tablet contains 20 mg of Finerenone / 30 tablets per bottle or 3 blisters of 10 tablets, both in a cardboard box with a leaflet.

References:
1. www.medicines.org.uk/emc(Medicines Compendium) (abpi)
2. www.ema.europa.eu/en/medicines/human/EPAR/kerendia
3. www.accessdata.fda.gov

Last Revised: 2025/08/30