FinFit™

Finerenone INN

COMPOSITION

FinFit™ 10 Tablet: Each film coated tablet contains Finerenone INN 10 mg.

PHARMACOLOGY

Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription. Finerenone blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation. Finerenone has a high potency and selectivity for the MR and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors.

INDICATION

FinFit™ tablet is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, nonfatal 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 starting dose of **FinFit™** is based on eGFR:

eGFR (mL/min/1.73m2)	Starting Dose
≥ 60	20 mg once daily
≥ 25 to < 60	10 mg once daily
< 25	Not Recommended

For patients who are unable to swallow whole tablets, **FinFit™** may be crushed and mixed with water or soft foods such as applesauce immediately prior to use and administered orally.

Monitoring and Dose Adjustment

The target daily dose of **FinFit™** is 20 mg.

Measure serum potassium 4 weeks after initiating treatment and adjust dose; if serum potassium levels are > 4.8 to 5.0 mEq/L, initiation of **FinFit™** treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on clinical judgement and serum potassium levels. Monitor serum potassium 4 weeks after a dose adjustment and throughout treatment, and adjust the dose as needed.

Dose Adjustment Based on Current Serum Potassium Concentration and Current Dose

		Current FinFit™ Dose	
		10 mg once daily	**20 mg once daily**
Current Serum Potassium (mEq/L)	≤ 4.8	Increase the dose to 20 mg once daily.*	Maintain 20 mg once daily.
	> 4.8 – 5.5	Maintain 10 mg once daily.	Maintain 20 mg once daily.
	> 5.5	Withhold FinFit™ Consider restarting at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.	Withhold FinFit™ Restart at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.

* If eGFR has decreased by more than 30% compared to previous measurement, maintain 10 mg dose.

Missed doses

Direct a patient to take a missed dose as soon as possible after it is noticed, but only on the same day. If this is not possible, the patient should skip the dose and continue with the next dose as prescribed.

SIDE EFFECTS

Hyperkalemia.

CONTR AINDICATIONS

FinFit™ is contraindicated in patients:

•Who are receiving concomitant treatment with strong CYP3A4 inhibitors

•With adrenal insufficiency

WARNINGS AND PRECAUTIONS

Hyperkalemia

Kerendia can cause hyperkalemia. The risk for developing hyperkalemia increases with decreasing kidney function and is greater in patients with higher baseline potassium levels or other risk factors for hyperkalemia. Measure serum potassium and eGFR in all patients before initiation of treatment with FinFit™ and dose accordingly. Do not initiate FinFit™ if serum potassium is > 5.0 mEq/L.

Measure serum potassium periodically during treatment with FinFit™ and adjust dose. More frequent monitoring may be necessary for patients at risk for hyperkalemia, including those on concomitant medications that impair potassium excretion or increase serum potassium.

DRUG INTERACTIONS

CYP3A4 Inhibitors and Inducers.

Strong CYP3A4 Inhibitors

FinFit™ is a CYP3A4 substrate. Concomitant use with a strong CYP3A4 inhibitor increases Finerenone exposure which may increase the risk of FinFit™ adverse reactions. Concomitant use of FinFit™ with strong CYP3A4 inhibitors is contraindicated. Avoid concomitant intake of grapefruit or grapefruit juice.

Moderate and Weak CYP3A4 Inhibitors

FinFit™ is a CYP3A4 substrate. Concomitant use with a moderate or weak CYP3A4 inhibitor increases finerenone exposure which may increase the risk of FinFit™ adverse reactions. Monitor serum potassium during drug initiation or dosage adjustment of either FinFit™ or the moderate or weak CYP3A4 inhibitor, and adjust FinFit™ dosage as appropriate and Drug Interaction.

Strong and Moderate CYP3A4 Inducers

FinFit™ is a CYP3A4 substrate. Concomitant use of FinFit™ with a strong or moderate CYP3A4 inducer decreases Finerenone exposure which may reduce the efficacy of FinFit™. Avoid concomitant use of FinFit™ with strong or moderate CYP3A4 inducers.

USE IN SPECIFIC POPULATIONS

Use in Pregnancy & Lactation

There are no available data on FinFit™ use in pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

There are no data on the presence of FinFit™ or its metabolite in human milk, the effects on the breastfed infant or the effects of the drug on milk production.

Pediatric Use

The safety and efficacy of FinFit™ have not been established in patients below 18 years of age.

Geriatric Use

Of the 2827 patients who received FinFit™ in the FIDELIO-DKD study, 58% of patients were 65 years and older, and 15% were 75 years and older. No overall differences in safety or efficacy were observed between these patients and younger patients. No dose adjustment is required.

Hepatic Impairment

Avoid use of FinFit™ in patients with severe hepatic impairment (Child Pugh C). No dosage adjustment is recommended in patients with mild or moderate hepatic impairment (Child Pugh A or B). Consider additional serum potassium monitoring in patients with moderate hepatic impairment

OVERDOSE

In the event of suspected overdose, immediately interrupt FinFit™ treatment. The most likely manifestation of overdose is hyperkalemia. If hyperkalemia develops, standard treatment should be initiated.

Finerenone is unlikely to be efficiently removed by hemodialysis given its fraction bound to plasma proteins of about 90%.

STORAGE

Store below 30°C, Keep in a dry place, Protect from light. Keep all medicine out of reach of children.

HOW SUPPLIED

FinFit™ 10 Tablet: Each box contains 10 tablets in Alu-Alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS PLC.
Kaliakoir, Gazipur, Bangladesh

TM- Trade Mark