Prescribing Information Document
Finerenone for treating chronic kidney disease in type 2 diabetes

1. Introduction

The document aims to support initiation and prescribing of finerenone in adults with chronic kidney disease (CKD) and type 2 diabetes (T2DM) across Herts and West Essex ICS.

HWE ICS approved indications for use

Finerenone is recommended in line with NICE TA877 as an option for treating stage 3 and 4 chronic kidney disease (with albuminuria, that is, an albumin to creatinine ratio (uACR) that is persistently 3 mg/mmol [30 mg/g] or more) associated with type 2 diabetes in adults if
- it is an add-on to optimised standard care; this should include, unless they are unsuitable, the highest tolerated licensed doses of:
  ○ angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) and
  ○ sodium–glucose cotransporter 2 (SGLT2) inhibitors and
- the person has an estimated glomerular filtration rate (eGFR) of 25 ml/min/1.73 m2 or more

2. Areas of responsibility

GREEN RAG rating; Recommended for prescribing and treatment considered to be suitable for initiation in Primary, Community, Secondary or Tertiary care and continuation in Primary Care.

1.	Initiate finerenone in patients with chronic kidney disease and type 2 diabetes in line with criteria recommended in NICE TA877 (see 'HWE ICS approved indications for use') At initiation exclude contraindications and consider precautions for use (see section 3.3). *Where initiated by specialist; following treatment stabilisation and no further dose changes anticipated, request ongoing prescribing via letter to the GP for treatment continuation. (see also below recommended monitoring following initiation).*
2.	Perform baseline monitoring tests to inform if treatment should be started and dosing advice (see section 3.1): serum potassium level, eGFR

3.	Discuss treatment with finerenone with the patient including;
	- *Indication for use*
	- counselling points; *to include but not limited to:*
	  • *Advise on dosage and frequency.*
	  • *Advise patient to report any of the following signs or symptoms to their GP or initiating clinician without delay*
	  Palpitations,
	  Shortness of breath,
	  Chest pain,
	  Nausea and/or vomiting
	  • *Advise patient to avoid grapefruit and not to drink grapefruit juice during treatment with finerenone as it can increase exposure to finerenone.*
	  • *Where relevant*
	  • *Patients unable to swallow whole tablets; advise that tablets may be crushed and mixed with water or foods*
	  • *Advice in pregnancy and breastfeeding (follow advice as listed in SPC)*
	  • *Refer to patient information leaflet from SPC (link)*

	- Ongoing requirement for monitoring/review - Patients or their carers should be advised to seek help if side effects are suspected. Ensure the patients understand the nature and complications of drug therapy and their role in reporting adverse effects promptly. see 'Patient/carer responsibilities'
4.	Check for possible drug interactions when newly prescribing or stopping concurrent medication
5	Provide ongoing monitoring and management of adverse effects (see further information below), and adjust dose as required for ongoing prescribing
6.	Seek advice from the specialist team regarding any concerns at each stage of treatment (Contact diabetes or renal specialist via Advice & Guidance)

Patient/Carer responsibilities	
1.	Report to their specialist or primary care clinician if they do not have a clear understanding of, or have any concerns with their treatment.
2.	Inform the specialist or primary care clinician if pregnant or planning a pregnancy while on treatment with finerenone.
3.	Report any adverse effects or worsening of condition to the specialist or primary care clinician whilst taking finerenone.
4.	Attend review appointments as requested.

3. Further information

Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR).

Overactivation of MR in the kidneys and heart contributes to inflammation and fibrosis—key processes driving chronic kidney disease and cardiovascular damage in diabetes. 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.

The introduction of finerenone provides an additional renal protection through a different mechanism to standard of care and in line with the recommendations by NICE TA877 can be considered as an add-on treatment to standard of care with ACE inhibitors/ or angiotensin receptor blockers (ARBs) and SGLT2i for patients with stage 3 or 4 chronic kidney disease (CKD) with albuminuria and type 2 diabetes (T2DM).

Regular monitoring of potassium levels and eGFR would be required to determine the treatment dose.

3.1 Dosing advice:

Initiating therapy:

Serum potassium level (mmol/L)	
≤ 4.8	Start finerenone
> 4.8 to 5.0	Finerenone may be considered with additional serum potassium monitoring within the first 4 weeks based on patient characteristics and serum potassium levels
> 5.0	Do not start finerenone
eGFR (mL/min/1.73 m^2)	
≥ 25 to < 60	Start 10mg daily
< 25	Do not start finerenone

Check serum potassium and eGFR after 4 weeks of initiation, after restarting treatment or after dose increase.

Continuation of therapy: In patients with eGFR ≥ 15 mL/min/1.73 m2, finerenone treatment can be continued with dose adjustment based on serum potassium.

Continuation of finerenone treatment and dose adjustment:

Serum potassium level (mmol/L)	Current finerenone dose (once daily)	
	10mg	20mg
≤ 4.8	Increase to 20 mg finerenone once daily (Maintain 10mg daily if eGFR has decreased more than 30% compared to the previous measurement)	Continue
> 4.8 to 5.5	Continue	Continue
> 5.5	Withhold finerenone. Re-start at 10 mg once daily when serum potassium ≤ 5.0 mmol/L.	
eGFR: Stop finerenone in end-stage renal disease with eGFR <15mL/min/1.73m^2		

3.2 Monitoring and managing adverse reaction:

eGFR and Potassium		
To be completed by initiating clinician (specialist or primary care clinician)		Continuation
Baseline prior to initiation	4 weeks after initiation or re-start of treatment or after dose change	Ongoing monitoring periodically. Recommended frequency in line with NICE CG203 (recommend usually every 4-6 months in CKD 3 and every 3 months in CKD 4 or as required based on patient specific factors as included in NICE CG203).
Sodium (included in standard U&Es) and Hb (FBC)		
		As required and as side effects suspected as part of routine monitoring

Adverse reactions and management	
This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme https://yellowcard.mhra.gov.uk/	
Of particular note:	**Action to take**
Hyperkalaemia (very common)	Repeat eGFR and serum potassium level Consider reducing finerenone dose or suspend treatment as required (*see dose adjustment table*) Primary care clinicians - contact specialist services for further advice if needed
Hyponatraemia (common)	Identify other causes of hyponatraemia: - Renal losses, i.e., diuretics, hypoadrenalism, sodium-losing nephropathies - Non-renal losses, i.e., diarrhoea, vomiting, pancreatitis - Oedematous states such as severe renal impairment, congestive heart failure, cirrhosis - Hypothyroidism - Psychogenic polydipsia Primary care clinicians - contact specialist services for further advice if needed
Decreased level of haemoglobin (uncommon)	Identify other causes of decrease in haemoglobin: - cancer

	- medications, e.g. antiretrovirals - cirrhosis - iron deficiency - vitamin deficiency - bleeding events Primary care clinicians - contact specialist services for further advice if needed
Other common side effects of note: Hypotension: SPC includes that the majority of hypotension events were mild or moderate and *resolved* in patients treated with finerenone. The mean systolic blood pressure decreased by 2-4 mm Hg and the mean diastolic blood pressure decreased by 1-2 mm Hg at month 1, remaining stable thereafter. The risk for hypotension increases with concomitant use of multiple other antihypertensive medicinal products. Blood pressure monitoring is recommended. eGFR decrease: SPC notes the majority of GFR decreased events were mild or moderate and *resolved* in patients treated with finerenone, experiencing an initial decrease in eGFR (mean 2 mL/min/1.73 m2) that attenuated over time compared to placebo. This decrease appeared to be reversible during continuous treatment. Hyperuricaemia SPC notes an increase from baseline in mean serum uric acid of 0.3 mg/dL was seen in the finerenone group compared to placebo up to month 16, which attenuated over time. No difference between the finerenone group and the placebo group was observed for reported events of gout.	
* Refer to SPC for complete and up to date list of side effects.	

3.3 Contra-indications and cautions:

Establish no contra-indications and assess cautions:

Contraindications:

Hypersensitivity to the active substance or to any of the excipients

Addison's disease

Severe hepatic impairment

Concomitant treatment with strong inhibitors of CYP3A4 (e.g. ketoconazole, itraconazole, ritonavir, nelfinavir, cobicistat, clarithromycin telithromycin or nefazodone)

Cautions:

moderate hepatic impairment; consider additional monitoring due to increased finerenone exposure.

The risk of hyperkalaemia also may increase with the intake of concomitant medications that may increase serum potassium.

Finerenone should not be given concomitantly with

- potassium-sparing diuretics (e.g. amiloride, triamterene) and
- other mineralocorticoid receptor antagonists (MRAs), e.g. eplerenone, spironolactone

Finerenone should be used with caution and serum potassium should be monitored when taken concomitantly with

- potassium supplements
- trimethoprim or trimethoprim/sulfamethoxazole. Temporary discontinuation of finerenone may be necessary

refer to SPC for complete and up to date list of contraindications & cautions.

3.4 Drug interactions:

Interactions of particular note are also listed above in contra-indications & cautions *section 3.3*

Concomitant treatment with **strong inhibitors of CYP3A4 is contraindicated** (e.g. ketoconazole, itraconazole, ritonavir, nelfinavir, cobicistat, clarithromycin telithromycin or nefazodone) since a marked increase in finerenone exposure is expected.

Serum potassium should be monitored during concomitant use of finerenone with **moderate (e.g. erythromycin) or weak CYP3A4 inhibitors. (Concomitant use with precautions)**
Serum potassium may increase, and therefore, monitoring of serum potassium is recommended, especially during initiation or changes to dosing of finerenone or the CYP3A4 inhibitor.

Concomitant treatment with **strong inducers of CYP3A4 is not recommended** (e.g. rifampicin, carbamazepine, phenytoin, phenobarbital, St John's Wort) or **with moderate CYP3A4 inducers** (e.g. efavirenz). These are expected to decrease finerenone plasma concentration and result in reduced therapeutic effect.

Concomitant use of multiple other antihypertensive medicinal products increased the risk for hypotension. Blood pressure monitoring is recommended.

See section 3.3 *medicinal products that increase serum potassium*

refer to SPC for complete and up to date list of drug interactions

---

4. References

1) Electronic Medicines Compendium, SPC finerenone, accessed via medicines.org.uk (accessed November 2025)
2) Finerenone for treating chronic kidney disease in type 2 diabetes TA877, published 23 March 2023 (link)
3) Chronic kidney disease: assessment and management, NICE guideline 203, published 25 August 2021, last updated 24 November 2021

5. Acknowledgment

Adapted from BLMK ICB guidance; Prescribing Guidance for Finerenone for treating chronic kidney disease (CKD) with type 2 diabetes (T2DM) & Finerenone Prescribing/ Monitoring Checklist for Diabetic Kidney Disease (February 2025)

Version: 1.0

Developed by: HWE ICS PMOT in collaboration with Consultant Renal Pharmacist East and North Herts NHS Trust
Approved by: HWE APC
Date approved: December 2025
Review date: The document is based upon the information available at the time of publication. This document will be reviewed upon request in light of new information becoming available.
Superseded: n/a