SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Renodyra 1080 mg modified-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1080 mg (10 mEq) of potassium citrate, equivalent to 390 mg of potassium.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified-release tablet.
Cream coloured to yellow, oval, biconvex, uncoated tablets (length: 18.50 mm).

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Renodyra is an alkalizing agent and indicated in adults for:

– The treatment of patients with kidney stones and hypocitraturia, or chronic calcium oxalate stones.

– The treatment and prevention of recurrent uric acid lithiasis with or without calcium lithiasis and cystine lithiasis.

– The treatment of renal tubular acidosis with calcium nephrolithiasis.

4.2 Posology and method of administration

Posology

In patients with severe hypocitraturia (urinary citrate <150 mg/day), therapy should be initiated at a dosage of 6480 mg (60 mEq) per day (6 tablets) divided into 3 intakes per day.

In patients with mild hypocitraturia (urinary citrate >150 mg/day), therapy should be initiated at a dosage of 3240 mg (30 mEq) per day (3 tablets) divided into 3 intakes per day.

If necessary, the dosage may be increased as long as the 10800 mg (100 mEq)/day limit is not exceeded.

Renal impairment
Renodyra is contraindicated in individuals with glomerular filtration rate (GFR) ≤44 mL/min/1.73m^2 (see section 4.3). For individuals with a GFR between 45 and 59 mL/min/1.73m^2 and plasma potassium levels in the normal ranges, regular monitoring of renal function parameters and blood potassium levels is recommended (see section 4.4).

Potassium citrate is contraindicated in patients with elevated plasma potassium levels (see section 4.3).

Hepatic impairment
Potassium citrate should be used with caution in patients with hepatic impairment (see section 4.4).

Paediatric population
The safety and efficacy of Renodyra in children have not been established. No data are available.

Method of administration
Renodyra is administered orally.

The tablets should be taken with meals or within 30 minutes after meals to avoid gastrointestinal reactions.

The tablets must be swallowed whole with enough liquid and should not be taken with alcohol, crushed, chewed or dissolved as this may result in the medicine being released too early.

The tablets should be taken in conjunction with a diet that avoids foods with high sodium content and avoids the use of table salts. Patients who take Renodyra modified-release tablets should increase their fluid intake.

It is recommended that 24-hour urinary citrate and urinary pH measurement is used to determine the adequacy of the initial dosage and to evaluate the effectiveness of any dosage change. In the case of a pH value which is higher or lower than the target range of 6.0 to 7.0, the daily dose should be adjusted in accordance with the needs of the patient. This is preferably done with the evening dose.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Renal impairment (GFR ≤ 44 mL/min/1.73 m^2)
- Active or persistent urinary tract infections
- Significant or complete obstruction of the urinary tract
- Hyperkalaemia

- Severe myocardial injury
- Uncontrolled diabetes mellitus
- Adrenal insufficiency
- Metabolic or respiratory alkalosis
- Active peptic ulcer
- Delayed gastric emptying
- Intestinal obstruction

4.4 Special warnings and precautions for use

Hyperkalaemia and cardiotoxicity

In patients with impaired mechanisms for excreting potassium, the administration of Renodyra may produce hyperkalaemia and cardiac arrest. Potentially fatal hyperkalaemia may develop rapidly and be asymptomatic.

Renodyra should be used with caution in case of combination with other products increasing plasma potassium or predisposing to cardiac arrest (see section 4.5).

Serum electrolytes (sodium, potassium, chloride and carbon dioxide), serum creatinine, and complete blood count should be monitored every four months.

Severe hepatic impairment

There is the potential for hyperkalaemia and citrate toxicity in severe hepatic impairment though the impact of oral potassium citrate in these patients has not been studied (see section 4.2).

Renal impairment

For individuals with a GFR between 45 and 59 mL/min/1.73m^2 and plasma potassium levels in the normal ranges, regular monitoring of renal function parameters and blood potassium levels is recommended at starting dose, after new dose increase or in case of decreased GFR. Then frequency should be according to the physician's criteria, but at least twice a year.

Excipients

This medicinal product contains 390 mg potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use should be avoided

Amphetamines	Alkalinizing agents may decrease the excretion of amphetamines. Management: Consider alternatives to using amphetamines and alkalinizing agents in combination. If these agents must be used together, patients should be monitored

	closely for excessive amphetamine effects. Modification of therapy should be considered.
Anticholinergic agents	May enhance the ulcerogenic effect of potassium citrate.
Potassium-sparing diuretics (i.e., amiloride, eplerenone, spironolactone, triamterene)	Potassium salts may enhance the hyperkalaemic effect of potassium-sparing diuretics. Management: This combination should only be used in cases of significant hypokalaemia, and only if serum potassium can be closely monitored. Modification of therapy should be considered.

Concomitant use requires monitoring

ACE inhibitors	May enhance the hyperkalaemic effect of potassium salts.
Aliskiren	Potassium salts may enhance the hyperkalaemic effect of aliskiren.
Alpha-/beta-agonists (indirect-acting)	Alkalinizing agents may increase the serum concentration of alpha-/beta-agonists (indirect-acting).
Aluminium hydroxide	Citric acid derivatives may increase the absorption of aluminium hydroxide.
Amantadine	Alkalinizing agents may increase the serum concentration of amantadine.
Angiotensin II receptor blockers	Potassium salts may enhance the hyperkalaemic effect of angiotensin II receptor blockers.
Beta-blockers	May enhance the hyperkalaemic effect of potassium salts.
Digoxin	May enhance the hyperkalaemic effect of potassium salts.
Drospirenone-containing products	May enhance the hyperkalaemic effect of potassium salts.
Finerenone	Potassium salts may enhance the hyperkalaemic effect of finerenone.
Heparin (incl. low-molecular weight)	May enhance the hyperkalaemic effect of potassium salts.
Mecamylamine	Alkalinizing agents may increase the serum concentration of mecamylamine.
Memantine	Alkalinizing agents may increase the serum concentration of memantine.
Nicorandil	May enhance the hyperkalaemic effect of potassium salts.

Nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., indomethacin)	May enhance the hyperkalaemic effect of potassium salts.
Quinine	Alkalinizing agents may increase the serum concentration of quinine.

Interaction with alcohol
Taking Renodyra with alcohol can lead to a loss of the modified-release effect (see section 4.2).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of Renodyra in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3).

Renodyra should only be used during pregnancy if the expected benefits outweigh the potential risks. Although during pregnancy and more so during labour, there is more risk associated to a potentially severe acidosis and hypokalaemia in dRTA patients than to alkali treatment, in women with problem pregnancies there might be an increased risk to develop hyperkalaemia when potassium intake is high.

Breast-feeding
Potassium is excreted in human milk, but at therapeutic doses of Renodyra no effects on the breastfed newborns/infants are anticipated.

Renodyra can be used during breast-feeding.

Fertility
Potassium citrate is not known to affect fertility.

4.7 Effects on ability to drive and use machines

Renodyra has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The most common adverse reaction relates to the formulation and potassium products causing gastro-intestinal upset including nausea, vomiting, diarrhoea, abdominal pain and discomfort, and can potentially lead to gastro-intestinal ulceration, bleeding, perforation and/or obstruction.

Adverse reactions are listed according to MedDRA organ classes and frequency. Frequencies are defined as: 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).

System organ class/frequency	MedDRA preferred term
Gastrointestinal disorders	
Very common	Abdominal pain, nausea
Common	Abdominal pain upper, diarrhoea, dyspepsia, dysphagia, oesophagitis, vomiting, gaseousness (bloating, belching, flatulence)
Not known	Gastrointestinal mucosal damage, gastrointestinal bleeding or obstruction
Metabolism and nutrition disorders	
Not known	Hyperkalaemia
Skin	
Common	Rash

In patients with rapid gastrointestinal transit time, the tablet wax matrix may be present in their faeces.

Description of selected adverse reactions
Ingestion of potassium citrate may induce hyperkalaemia.

Severe hyperkalaemia may lead to muscle weakness/paralysis and cardiac conduction abnormalities (e.g., heart block, ventricular arrhythmias, asystole). Patients with cardiovascular disease e.g., heart failure, cardiac arrhythmias, may be more susceptible to life-threatening cardiac effects associated with hyper/hypokalaemia and, therefore, potassium citrate should be used with caution (see section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal products. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms
Overdosage of Renodyra can cause hyperkalaemia. Disturbances caused by hyperkalaemia are mainly neuromuscular and cardiovascular.

Neuromuscular disturbances include depression, mental confusion, paraesthesia, muscle weakness and sometimes flaccid paralysis of the extremities, which can be progressive.

Cardiovascular disturbances include bradycardia, low blood pressure, which may in some cases be serious, leading to cardiac arrhythmias, cardiac arrest and sudden death.

Treatment
In case of overdose, administration of potassium should be stopped. Depending on the severity of hyperkalaemia, treatment may include rapid acting therapies to treat hyperkalaemia (calcium and insulin with glucose) and measures to remove potassium from the body (haemodialysis, gastrointestinal potassium binders, or diuretics). Patients should be ECG monitored.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: mineral supplements, potassium
ATC code: A12BA02

Administration of the medicinal product increases urinary pH and raises urinary citrate. During long-term administration the daily excreted amounts of potassium largely correlate with the daily given dose and an accumulation of potassium is unlikely in the case of intact renal function. In some patients, a transient decrease of urinary calcium can occur.

As a result of the alkalizing effect of Renodyra, the tendency for calcium oxalate and uric acid to crystallize is significantly decreased, with subsequent decreased tendency for development of renal lithiasis from these salts.

Furthermore, the increase in urine citrate content favours its combination with calcium salts, decreasing calcium ion activity and thus the saturation of calcium oxalate. The increase in urinary pH, both decreases the calcium ion activity to make its combination with dissociated anions easier and contributes to increase the ionization of uric acid.

Renodyra does not alter the urinary saturation of calcium phosphate, since the effect of increased citrate complexation of calcium is opposed by the rise in the pH-dependent dissociation of phosphate. Calcium phosphate stones are more stable in alkaline urine.

5.2 Pharmacokinetic properties

Renodyra is almost completely absorbed from the upper part of the gastrointestinal tract within 3 hours.

In patients with normal renal function, a rise in urinary citrate is observed within the first hour after administering Renodyra at a 2.160 mg (20 mEq)

dose and lasts approximately 12 hours. With multiple doses, the rise in citrate excretion reaches its peak by the third day. Renodyra averts the normally wide circadian fluctuation in urinary citrate, thus maintaining urinary citrate at a higher, more constant level throughout the day.

When the treatment with Renodyra is withdrawn, urinary citrate begins to return to pre-treatment levels.

Following long-term treatment, administering 6480 mg (60 mEq)/day increases urinary citrate and pH by approximately 400 mg/day and 0.7 units, respectively.

5.3 Preclinical safety data

Non-clinical data reveals no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carnauba Wax

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

This medicinal product is packed in a polyethylene (HDPE) bottle, closed with a tamper evident cap with an aluminium PE / PP / Al insert. The bottle is labelled and packed into a unit carton.

Pack size: 100 modified-release tablets.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Penlan Pharmaceuticals Ltd
45-47 Monument Hill, Weybridge,
KT13 8RN, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL56328/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/01/2025

10 DATE OF REVISION OF THE TEXT

17/12/2025