Vitaflo in Association With You

Renastart™ designed specifically for the dietary management of paediatric kidney disease

Renastart™ is a food for special medical purposes (FSMP) designed specifically for the dietary management of paediatric kidney disease. It is high in energy and low in protein, with low levels of potassium, phosphorus, calcium, chloride and vitamin A to compensate for impaired kidney function.

Renastart was developed in conjunction with leading UK paediatric renal dietitians. It is for use in the dietary management of kidney disease from birth to 10 years of age. Its formulation offers flexibility so that intakes can be adjusted to the specific medically determined nutritional requirements of the individual.

Renastart can be used in Chronic Kidney Disease (CKD) and Acute Kidney Injury (AKI). **Renastart** must be used in conjunction with breast milk, standard infant formula, standard paediatric enteral feeds or with permitted foods depending on the age and medical condition of the child. However, it can be used alone initially for a short time to decrease a very high plasma potassium level. This will be determined by the Healthcare Professional. **Renastart** can be given as a tube feed or as a drink.

Energy

One of the major goals of paediatric CKD management is normal growth and development and early nutritional intervention is key[1]. The Paediatric Renal Nutrition Taskforce (PRNT), a group of expert Paediatric Nephrologists and Paediatric Renal Dietitians from across the world, suggest the initial prescription for energy intake in children with CKD stages 2-5 and on dialysis (CKD 2-5D) should approximate that of healthy children of the same age[2]. However, it is recognised that there are several factors which may contribute to a poor energy intake in children with kidney disease including dietary restrictions, fluid restrictions, anorexia, nausea and vomiting, and altered taste sensation[1] and therefore a large proportion of younger children will require tube feeding in order to meet their nutritional requirements[2].

Renastart has a higher energy content compared to mature breast milk, standard infant formula and whole cows' milk to allow for more energy to be provided in a small volume. This is shown in table 1 overleaf. Renastart's powder presentation allows flexibility with dilutions to enable higher levels of calories to be delivered. Renastart can be concentrated to provide an energy content of up to 2kcal/ml.

Protein

The KDOQI Work Group (2009) recommends that dietary protein intake should be maintained at 100% to 140% of the Daily Recommended Intake (DRI) for ideal body weight for children with Chronic Kidney Disease (CKD) stage 3 and at 100% to 120% of the DRI for children with CKD stages 4 to 5[1]. This recommendation assumes energy intake is also achieved. The PRNT use a new term, Suggested Dietary Intake (SDI), to describe nutritional requirements in their recommendations. The SDI comprises a range of values from different countries nutritional guidelines[2]. The PRNT suggest that the target protein intake in children with CKD 2-5D is at the upper end of the SDI range, however they also note that children with persistently high blood urea levels may require intakes closer to the lower end of the SDI[2]. The effect of protein restriction on the progression of CKD has been studied in both

the paediatric and adult population. Whilst there is no evidence for protein restriction having a nephroprotective effect, the evidence suggests that intake can be safely reduced to 0.98–1.1 g/kg[3]. This could delay uremia as protein restriction reduces nitrogenous waste products and can assist with lowering phosphate intake.

Based on this evidence, Renastart has been formulated to have a lower level of protein per 100kcal compared to standard infant formula to ensure that it can be used in conjunction with standard infant formula or oral diet without exceeding protein requirements and to meet the varying nutritional requirements of infants and children at the various stages of CKD. The concentration of Renastart can be adjusted to ensure that protein and energy requirements are met in conjunction with fluid restrictions.

Table 1: Comparison of the energy and protein content of Renastart, breast milk, standard infant formula and cows' milk

Per 100ml	Energy (kcal)	Protein (g)
Mature breast milk[1]	69	1.3
Infant formula standard dilution[2]	66	1.3
Whole cows' milk*[3]	63	3.4
Renastart 20% dilution[4]	100	1.5

* Whole cows' milk typically contains 3.7g fat/100ml.

1 Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285. 2019.

2 Source: Average of 3 infant formulas widely available in the UK, calculated from manufacturers data.

3 Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285. 2019.

4 Renastart 20% dilution: 20g Renastart made up to 100ml with water.

Potassium

The KDOQI Work Group (2009) recommend that potassium should be restricted in children with CKD 2-5D who have or are at risk of hyperkalaemia. Extracellular potassium influences muscle function and hypokalemia or hyperkalaemia can cause fatal cardiac arrhythmias[4]. Hyperkalemia is common in patients with CKD 5 and due to the risk of cardiac arrest the control of plasma potassium as part of the dietary management is critical. A reduced potassium diet is necessary and any nutritional supplements will be replaced with low potassium versions. There is no specific recommendation regarding the degree of restriction that needs to take place as it will depend on the individual child's biochemistry. However the KDOQI Work Group (2009) recommend that for infants and young children a restriction of 1-3 mmol/kg/day is a useful starting point[1].

Renastart is formulated with a lower level of potassium compared to mature breast milk, standard infant formula, standard paediatric enteral feeds and whole cows' milk as shown in table 2. It is formulated to ensure that, when used in conjunction with breast milk, infant formula and standard paediatric feeds, intakes remain within a typical potassium dietary restriction. Renastart can also be used to allow a more liberal oral diet which could enable experiences around food and mealtimes to be more positive which is important in this patient group[5].

Table 2: The potassium content of mature breast milk, standard infant formula, standard paediatric enteral feeds, whole cows' milk and Renastart.

Per 100ml	Potassium mg/mmol
Mature breast milk[1]	58 / 1.5
Standard infant formula (whey based)[2]	64 / 1.6
Standard paediatric enteral feed (1kcal/ml)[3]	112 / 2.8
Whole cows' milk*[4]	157 / 3.9
Renastart 20% dilution[5]	22 / 0.6

* Whole cows' milk typically contains 3.7g fat/100ml.
1 Source: McCance and Widdowson's The Composition of Foods, Integrated Data Set PHE publications gateway number: GW-285. 2019.
2 Source: Average of 3 infant formulas widely available in the UK, calculated from manufacturers data.
3 Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
4 Source: McCance and Widdowson's The Composition of Foods, Integrated Data Set PHE publications gateway number: GW-285. 2019.
5 Renastart 20% dilution: 20g Renastart made up to 100ml with water.

Phosphorus

Plasma phosphorus concentrations above the normal range should be avoided in all patients with CKD. Even when serum phosphorus levels are within the normal range, dietary phosphorus load remains a key factor regarding the severity of hyperparathyroidism. The management of Chronic Kidney Disease Mineral Bone Disorder (CKD-MBD) is a combination of limiting dietary phosphate intake and using phosphate binders. Avoidance of hyperphosphatemia is of key importance to help minimise the risk of developing CKD-MBD and the development of cardiovascular disease in paediatric renal patients[6]. In infants, a whey based formula is recommended as it has a lower phosphate content than casein[1, 7]. If hyperphosphatemia continues then a renal specific infant FSMP is used. Dietary phosphate intake is an important factor in the severity of hyperparathyroidism even in the early stages[7]. Studies have shown that in patients with CKD 3, a restriction of dietary phosphorus leads to a decrease in PTH levels and an increase in 1,25 hydroxy vitamin D production, whereas higher intakes of phosphorus (twice the DRI for age) lead to hyperparathyroidism with little or no difference in serum phosphorus levels[1, 8, 9].

Based on the evidence around phosphorus restriction, the KDOQI guidelines suggest restriction of dietary phosphorus to 100% of the DRI in patients with a serum PTH above target and normal serum phosphorus levels in children with CKD stage 3-5[1]. In children with a high PTH and high serum phosphorus it is recommended that intakes are restricted to 80% of the DRI[1]. Similarly, the PRNT suggest that the dietary phosphorus intake of children with CKD 2-5D should be within the SDI for age, without compromising adequate nutrition[7]. The PRNT also suggest that those with raised serum phosphorus or raised serum PTH will require further dietary restriction of phosphorus, potentially to the lower limit of the SDI, without compromising adequate nutrition[7].

Renastart is formulated with lower levels of phosphorus compared to standard infant formula, standard paediatric enteral feeds and whole cows' milk to enable dietary phosphate restrictions to be adhered to, in line with both the KDOQI guidelines and PRNT recommendations, whilst meeting energy and protein requirements. Using a supplementary feed which is low in phosphorus, such as Renastart, can enable a more liberal oral diet if the patient is able to eat. Renastart is also a whey based formula.

Calcium

In children with CKD both inadequate and excessive intakes of calcium can occur. Calcium homeostasis is disrupted in the early stages of CKD and continues to decline as kidney function worsens and is therefore most severely affected in CKD 5 and when on dialysis[7]. The maintenance of calcium balance is dependent on absorption and secretion in the intestine, excretion by the kidney as well as release and absorption from bone.

In CKD, intestinal absorption of calcium is reduced as the production of active vitamin D decreases. It is however stimulated by vitamin D therapy. There is evidence to suggest that a significantly positive calcium balance is a major contributing factor to soft tissue calcification[10]. KDOQI therefore recommend that total oral/enteral calcium intake from nutritional sources and phosphate binders be limited to a range of 100-200% of the DRI[1]. The PRNT suggest calcium intake from diet and medications should be within the SDI, and be no more than twice the SDI, unless in exceptional circumstances[7]. The first line phosphate binder used in children is calcium carbonate[6].

Renastart is formulated with lower calcium levels compared to standard infant formula, standard paediatric enteral feeds and whole cows' milk as shown in table 3, to minimise the risk of exceeding the recommendations around calcium intake, and to allow for the use of calcium-based phosphate binders, a common practice used to manage high serum phosphate levels (hyperphosphatemia) in kidney disease.

Table 3: The phosphorus and calcium content of mature breast milk, standard infant formula, standard paediatric enteral feeds, whole cows' milk and Renastart.

Per 100ml	Phosphorus (mg/mmol)	Calcium (mg/mmol)
Mature breast milk[1]	15 / 0.5	34 / 0.9
Infant formula standard dilution[2]	25 / 0.8	45 / 1.1
Standard paediatric enteral feeds[3]	52 / 1.7	58 / 1.5
Whole cows' milk*[4]	96 / 3.1	120 / 3
Renastart 20% dilution[5]	19 / 0.6	24 / 0.6

* Whole cows' milk typically contains 3.7g fat/100ml.
1 Source: McCance and Widdowson's The Composition of Foods, Integrated Data Set PHE publications gateway number: GW-285. 2019.
2 Source: Average of 3 infant formulas widely available in the UK, calculated from manufacturers data.
3 Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
4 Source: McCance and Widdowson's The Composition of Foods, Integrated Data Set PHE publications gateway number: GW-285. 2019.
5 Renastart 20% dilution: 20g Renastart made up to 100ml with water.

Sodium

Sodium requirements vary according to the type of renal disease in children[11]. Several of the most common causes of CKD in infancy are associated with sodium wasting. Growth in children with CKD may be hampered if ongoing sodium and water losses are not corrected[6].

Therefore, Renastart has been formulated to have a higher level of sodium than standard infant formula.

Table 4: The sodium content of mature breast milk, standard infant formula, standard paediatric enteral feeds, cows' milk and Renastart.

Per 100ml	Sodium (mg / mmol)
Mature breast milk[1]	15 / 0.6
Infant formula standard dilution[2]	17 / 0.7
Standard paediatric enteral feed[3]	60 / 2.6
Whole cows milk[4]	42 / 1.8
Renastart 20% dilution[5]	48 / 2.1

1 Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285. 2019.
2 Source: Average of 3 infant formulas widely available in the UK, calculated from manufacturers data.
3 Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
4 Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285. 2019.
5 Renastart 20% dilution: 20g Renastart made up to 100ml with water. It has a lower level of sodium compared to standard paediatric enteral feeds.

Vitamin A

The kidneys play an important role in the metabolism and excretion of vitamin A. In healthy individuals dietary vitamin A is converted into retinol, stored in the liver and transported to its target cells by carrier proteins. Retinol is then oxidized to its activated form and then degraded and filtered by the kidneys. Patients with kidney disease have been found to have high circulating levels of retinol. The reason for this may be reduced glomerular filtration rate or reduced conversion of retinol to its active form retinoic acid. The KDOQI Work Group (2009) recommends that the total intake of vitamin A should be limited to DRI for age[1]. More recently, it was found that hypervitaminosis A is seen very early on in children with CKD and is associated with increased dietary intake particularly from supplementary feeds[12].

Renastart has a lower level of vitamin A compared to mature breast milk, standard infant formula and standard paediatric enteral feeds, as shown in table 5, to enable the avoidance of excessive vitamin A intakes and potential risk of hypervitaminosis A.

Table 5: The vitamin A content of mature breast milk, standard infant formula, standard paediatric enteral feeds and Renastart.

Per 100ml	Vitamin A IU/µg
Mature breast milk[1]	205 / 62
Infant formula standard dilution[2]	193 / 58
Standard paediatric enteral feed[3]	143 / 41
Renastart 20% dilution[4]	87 / 26

1 Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285. 2019.

2 Source: Average of 3 infant formulas widely available in the UK, calculated from manufacturers data.

3 Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.

4 20% dilution: 20g Renastart made up to 100ml with water.

Renastart can be used as an enteral tube feed or taken as a drink:

Enteral tube feed: Renastart can be used alongside breast milk, standard infant formula, standard paediatric enteral feeds and/or other products, for example glucose polymers, as part of a modular feed, to provide additional energy and protein without excessively increasing potassium and phosphate intake.

Oral feed: Renastart can be made up as a drink and flavoured using low potassium / phosphate ingredients.

Renastart can be used from birth to 10 years of age:

In infancy: To replace standard infant formula **(short term only)** during periods of hyperkalaemia or used in combination with breast milk or standard infant formula.

In weaning: Can be used in conjunction with breast milk or standard formula to allow a wider range of foods to be introduced into the diet, taking into account the dietary restrictions necessary for the dietary management of kidney disease.

In childhood: Can be used as an alternative to cows' milk to provide extra energy without excessively increasing potassium and phosphate intake. **Renastart** can be taken as an unflavoured drink or incorporated into other permitted drink recipes.

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Important notice: Renastart is a Food for Special Medical Purposes and must only be used under strict medical supervision with regular monitoring of nutritional status and electrolyte levels.

Renastart is for enteral use only and is not suitable as a sole source of nutrition.

Innovation in Nutrition

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All information correct at the time of print

This information sheet is only intended for Healthcare Professionals

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