Vitaflo in Association With You

Renastep™ designed specifically for the dietary management of kidney disease for those aged 3 years onwards

Renastep was developed in line with globally recognised evidence based guidelines for the dietary management of paediatric kidney disease; The Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Nutrition in Children with CKD, 2008 Update (KDOQI Guidelines)[1] and in liaison with the Paediatric Renal Interest Nutrition Group (PRING)*.

Renastep is designed to meet the nutritional and practical needs of children aged 3 years onwards with kidney disease. It is a ready to use, high energy, low volume feed with low levels of potassium, phosphorus, calcium, chloride and vitamin A. It can be administered as a tube feed or taken orally. It can also be added to food or drinks.

Renastep is the first ready to use, paediatric renal specific feed designed to meet the needs of children with kidney disease who require a restricted potassium and / or restricted phosphate intake.

Ready to use liquid

For children aged 3 years onwards who are attending nursery or school, preparing powdered products and / or making complex feeding recipes can be impractical[2]. Renastep is a ready to use liquid feed and thus offers the benefit of reducing the number of steps needing to be followed to make up a bespoke feed. It may prove beneficial if there are any concerns regarding the accuracy of making up a powdered product. This format may also be of benefit for those children who wish to increase their intake orally.

Renastep is a ready to use liquid and has a 125ml bottle presentation that offers the advantage of being portable and thus convenient and easy to use for school aged children.

* PRING are a group of specialist Paediatric Renal Dietitians in the UK.

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Energy

One of the major goals in the management of paediatric kidney disease is to achieve normal growth and development. Therefore early nutrition intervention is key[1].

The Paediatric Renal Nutrition Taskforce (PRNT), a group of expert paediatric nephrologists and paediatric renal dietitians from across the world, recommend that for children with chronic kidney disease (CKD) stages 2-5 and on dialysis, energy intake should be that of healthy children of the same chronological age[3]. If energy intake is significantly below the estimated average requirement (EAR) then this will contribute to poor growth. Therefore, provision of adequate energy for children with CKD is essential.

There are several factors which can contribute to a poor energy intake in children with kidney disease including dietary restrictions, fluid restrictions, anorexia, nausea, vomiting, reflux and altered taste perception[1]. The PRNT recommend that, in children who are experiencing poor weight gain and linear growth, energy intakes should be at the upper end of the Suggested Dietary Intake (SDI) in order to promote optimal growth[3].

Renastep is designed with a higher energy content (2kcal/ml) compared to standard paediatric enteral feeds, as shown in table 1. The higher energy content of Renastep allows for more energy to be provided in a smaller volume which can be useful for children following a fluid restriction.

Protein

The KDOQI guidelines recommend that dietary protein intake should be maintained at 100% to 140% of the daily recommended intake (DRI) for ideal body weight for children with CKD stage 3 and 100-120% of the DRI for children with CKD stage 4 to 5[1]. The KDOQI guidelines recommendation regarding protein assumes adequate energy is also achieved[1].

Recently published clinical practice recommendations (CPRs) by the PRNT suggest that the target protein intake in children with CKD 2-5 and on dialysis should be at the upper end of the SDI[3]. However, it is also noted that children with persistently high blood urea levels, once other causes for high blood urea have been excluded, may require protein intakes closer to the lower end of the SDI[3].

Renastep has a lower level of protein (2g/100kcal) compared to standard paediatric enteral feeds as shown in table 1. It provides sufficient protein to meet the needs for growth whilst taking into account reduced kidney function. This can help to ensure a bespoke feed can be made, tailored to the child's age, stage of CKD, biochemistry and nutritional status.

Table 1: Comparison of the energy and protein content of Renastep, Renastart, standard paediatric enteral feed, energy dense paediatric enteral feed and whole cow's milk.

Product	Energy (kcal) per 100ml	Protein (g) per 100ml	Protein (g) per 100kcal
Renastep	200	4.0	2.0
Renastart* (20% dilution)[1]	100	1.5	1.5
Standard paediatric enteral feed[2]	101	2.8	2.8
Energy dense paediatric enteral feed[3]	151	4.2	2.8
Whole cow's milk[4]	63	3.4	5.4

* Renastart™ is a high energy, powdered formula with low levels of protein, potassium, phosphorus, calcium, chloride and vitamin A, containing whey protein, amino acids, carbohydrate, fat, vitamins, minerals, trace elements, arachidonic acid (ARA) and docosahexaenoic acid (DHA). Renastart is a Food for Special Medical Purposes.

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Calculated from manufacturer's data regarding a standard paediatric enteral feed (1kcal/ml) widely available in the UK.
3. Source: Calculated from manufacturer's data regarding a high energy standard paediatric feed (1.5kcal/ml) widely available in the UK.
4. Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285.2019.

Potassium

The adjustment of potassium intake in children with CKD is critically important as hyperkalaemia can be life threatening[4]. 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. The PRNT also recommend that if a child has serum potassium levels which are recurrently above the normal range, then a low potassium feed, such as Renastep, should be used. This will enable a reduction in the intake of potassium and thus enable the management of serum potassium levels[4].

There is no specific recommendation regarding the degree of restriction needed as this will depend upon the individual child's biochemistry. However, the KDOQI Work Group (2009) and PRNT state that a restriction of 1-3mmol/kg/day for infants and children is a useful starting point[1, 4]. Frequent monitoring of serum electrolyte levels is needed[4].

The use of a low potassium feed is preferred over the use of potassium binding medications due to the unwanted effects on other minerals that occurs with the use of such medications[4].

Renastep may be used alone for **short periods of time** to decrease a high serum potassium level to within the normal range. It can also be used in conjunction with a standard paediatric enteral feed or oral diet to achieve the potassium intake required to maintain serum potassium levels within the normal range.

Renastep has a lower level of potassium compared to standard paediatric enteral feeds and cow's milk as shown in table 2. It is formulated to ensure that, when mixed with standard paediatric enteral feeds, intake remains within a typical potassium dietary restriction. This enables potassium restrictions to be adhered to in line with the KDOQI and PRNT guidelines, whilst providing sufficient energy and protein[1, 4].

Using a feed which is low in potassium can also enable a more liberal oral diet to be consumed[4]. This 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 Renastep, Renastart, standard paediatric enteral feed, energy dense paediatric enteral feed and whole cow's milk.

Feed	Potassium content mg/mmol per 100kcal
Renastep	17.5/0.45
Renastart 20% dilution[1]	22/0.6
Standard paediatric enteral feed[2]	110/2.8
Energy dense paediatric enteral feed[3]	100/2.5
Whole cow's milk[4]	250/6.3

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Calculated from manufacturer's data regarding a standard paediatric enteral feed (1kcal/ml) widely available in the UK.
3. Source: Calculated from manufacturer's data regarding a high energy standard paediatric feed (1.5kcal/ml) widely available in the UK.
4. Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285.2019.

Phosphorus

Serum phosphate control is essential in the management of paediatric kidney disease as hyperphosphatemia is associated with Chronic Kidney Disease Mineral Bone Disease (CKD-MBD) and cardiovascular disease[6]. Even when serum phosphate levels are within the normal range, dietary phosphate load is a key factor in the severity of hyperparathyroidism. Phosphate retention can start early in CKD and emerging evidence indicates that a dietary phosphate restriction may be beneficial in children with CKD before serum phosphate levels start to rise[7,8]. The PRNT state that it is important to limit dietary phosphate intake to within the SDI in the mild-moderate stages of CKD (except in children with renal tubular disorders) and to the lower limit of the SDI in patients with advanced CKD and persistent hyperphosphatemia or hyperparathyroidism[9]. This restriction equates to about 80% of the DRI and conforms to the KDOQI recommendation. It is important that adequate nutrition is not compromised with these restrictions[9].

The management of CKD-MBD is a combination of limiting dietary phosphate intake and using phosphate binders. The differences in bioavailability of dietary phosphate is important to consider.

Standard paediatric enteral feeds, which are not specifically designed for kidney disease, have a phosphorus content that is too high when used to meet the full energy requirements of children with kidney disease if the patient is on a phosphate restriction.

Table 3: Summary of Suggested Dietary Intake (SDI) for calcium and phosphate in children with CKD 2-5 and on dialysis

Age	SDI calcium (mg)	SDI phosphate (mg)
0 - <4 months	220	120
4 - <12 months	330 - 540	275 - 420
1 - 3 years	450 - 700	250 - 500
4 - 10 years	700 - 1000	440 - 800
11 - 17 years	900 - 1300	640 - 1250

For children with poor growth, reference to the SDI for height age may be appropriate.

This table is reproduced from: McAlister, L. , Pugh, P., Greenbaum, L. et al. The dietary management of calcium and phosphate in children with CKD stages 2-5 and on dialysis–clinical practice recommendation from the Pediatric Renal Nutrition Taskforce. Pediatric Nephrology, 2020. 35: 501–518, under the Creative Commons Licence (http://creativecommons.org/licenses/by/4.0/).

Dietary phosphate restriction is commonly needed in the management of chronic kidney disease to prevent long term complications, namely CKD mineral bone disease (CKD-MBD) and cardiovascular disease[7,9]. Renastep has a lower level of phosphorus compared to standard paediatric enteral feeds and cow's milk as shown in table 4, supporting dietary phosphate restrictions and thus management of serum phosphate levels.

Calcium

In children with CKD both inadequate and excessive intakes of calcium can occur. An inadequate intake may lead to demineralisation of bone. Calcium homeostasis is disrupted in the early stages of CKD and continues to decline as kidney function worsens.

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. Absorption 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]. The PRNT suggest calcium intake from diet and medications should be within the SDI, and no more than double the SDI, unless in exceptional circumstances[9]. The first line phosphate binder in children is calcium carbonate[6].

Renastep has lower levels of calcium compared to standard paediatric enteral feeds to allow the use of calcium-based phosphate binders, a common practice used to manage high serum phosphate levels (hyperphosphatemia). This avoids intakes in excess of that recommended in the KDOQI guidelines[1] and is aligned with PRNT guidelines.

Table 4: The phosphorus and calcium content of Renastep, Renastart, standard paediatric enteral feed, energy dense paediatric enteral feed and whole cow's milk.

Feed	Phosphorus (mg/mmol) per 100kcal	Calcium (mg/mmol) per 100kcal
Renastep	17.5/0.5	23/0.6
Renastart (20% dilution)[1]	19/0.6	24/0.6
Standard paediatric enteral feed (1kcal/ml)[2]	53/1.7	56 / 1.4
Energy dense paediatric enteral feed (1.5kcal/ml)[3]	50/1.6	60/1.5
Whole cow's milk[4]	152/4.9	190/4.8

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Calculated from manufacturer's data regarding a standard paediatric enteral feed (1kcal/ml) widely available in the UK.
3. Source: Calculated from manufacturer's data regarding a high energy standard paediatric feed (1.5kcal/ml) widely available in the UK.
4. Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285.2019.

Sodium

As CKD progresses, sodium and fluid retention become more common. This can lead to oedema and hypertension. A sodium and fluid restriction is usually advised alongside diuretic medications to manage fluid retention.

The KDOQI guidelines for hypertension, cardiovascular disease (CVD) and dialysis adequacy all state that dietary sodium restriction is a key component in volume and blood pressure control in children with CKD. The degree of restriction discussed in the KDOQI guidelines correlates to ~1-2 mmol/kg/d which correlates with the DRI[7].

Renastep has been formulated to be lower in sodium than standard paediatric enteral feeds per 100kcal as shown in table 5.

Table 5: The sodium content of Renastep, Renastart, standard paediatric enteral feed, energy dense paediatric enteral feed and whole cow's milk.

Feed	Sodium (mg/mmol) per 100kcal
Renastep	42/1.8
Renastart (20% dilution)[1]	48/2.1
Standard paediatric enteral feed[2]	60/2.6
Energy dense paediatric enteral feed[3]	60/2.6
Whole cow's milk[4]	67/2.9

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Calculated from manufacturer's data regarding a standard paediatric enteral feed (1kcal/ml) widely available in the UK.
3. Source: Calculated from manufacturer's data regarding a high energy standard paediatric feed (1.5kcal/ml) widely available in the UK.
4. Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285.2019.

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[11]. The reason for this may be the reduced glomerular filtration rate or the reduced conversion of retinol to its active form retinoic acid. The KDQOI guidelines recommend that total vitamin A intake should be limited to the DRI[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[11].

Renastep has a lower level of vitamin A compared to standard paediatric enteral feeds in line with the KDOQI guidelines so as to avoid excessive vitamin A intakes and potential hypervitaminosis A as shown in table 6.

Table 6. The vitamin A content of Renastep, Renastart, standard paediatric enteral feed, energy dense paediatric enteral feed and whole cow's milk.

Feed	Vitamin A content (mcg RE) per 100kcal
Renastep	19.5
Renastart (20% dilution)[1]	26
Standard paediatric enteral feed[2]	45
Energy dense paediatric enteral feed[3]	41
Whole cow's milk[4]	61

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Calculated from manufacturer's data regarding a standard paediatric enteral feed (1kcal/ml) widely available in the UK.
3. Source: Calculated from manufacturer's data regarding a high energy standard paediatric feed (1.5kcal/ml) widely available in the UK.
4. Source: McCance and Widdowson's The Composition of Foods Integrated Data Set PHE publications gateway number: GW-285.2019.

Micronutrients

The specific micronutrient requirements of children with CKD are not well defined. KDOQI guidelines state that the provision of at least 100% of the DRI for thiamine, riboflavin, niacin, pantothenic acid, pyridoxine, biotin, cobalamin, ascorbic acid, retinol, vitamin E, vitamin K, folic acid, copper and zinc should be considered for children with CKD stages 2 to 5 and 5D[1].

Renastep was formulated in line with the European Food Safety Authority (EFSA) dietary reference values (DRV) for children aged 3 years onwards for vitamins and minerals except for vitamin A, potassium, phosphorus, calcium and sodium to allow for the common restriction of these nutrients in the management of kidney disease[12].

Fat

According to the KDOQI guidelines, young children with CKD need a somewhat greater percentage of fat in their diet to meet their energy needs[1]. However, dyslipidemia is common among children with moderate CKD and this may contribute to the development of cardiovascular disease later in life[13]. Dietary advice to lower total fat intake for the management of dyslipidaemia is not recommended in children that are malnourished. However a switch to heart-healthy fats is recommended[1].

Renastep contains sunflower and rapeseed oils to provide as low a saturated fat content as possible due to the high prevalence of dyslipidemia among children with CKD[13].

Flavour / Acceptability

Encouraging positive oral experiences and oral diet is key in children with kidney disease[5]. Children with CKD often experience taste changes, a poor appetite and poor oral intake[2, 14].

Renastep is the first ready to use feed that is designed specifically for young children aged 3 years onwards with kidney disease. It has a mild vanilla flavour to accommodate the taste preferences of children aged 3 years onwards and has been shown to be palatable in this age group[15].

Renastep can be used flexibly:

As a tube feed:

- Alongside oral intake to allow a less restrictive diet.
- Alone for **short periods of time** to reduce a moderate to severely high serum potassium level, with careful monitoring of serum electrolyte levels.
- With a standard paediatric enteral feed to create a bespoke feed tailored to meet a child's nutritional requirements whilst managing serum potassium and phosphate levels.

As an oral supplement:

- When nutrition support is needed and a dietary potassium and / or phosphate restriction is needed.
- To give a nutritional top up in a palatable form, without the need for an enteral feeding tube.
- As a drink, made into "milkshakes" (when mixed with suitable fruits or syrups), or used to prepare foods such as porridge.

References

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

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

Renastep contains **milk** and **fish**.

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A Nestlé Health Science Company

Vitaflo International Ltd

Suite 1.11, South Harrington Building, 182 Sefton Street, Brunswick Business Park, Liverpool, L3 4BQ, UK.

Nutritional Helpline: **+44 (0) 151 702 4937** **www.vitafloweb.com**

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