Vitaflo in Association With You

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

Renastep has been developed in line with the latest globally recognised evidence based guidelines for the nutritional 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 has been 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.

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 that is easy to use as well as being sterile for tube feeding. The 125ml bottle presentation also offers the advantage of being portable which is convenient for school aged children.

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

Vitaflo®

Innovation in Nutrition

Energy

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

The energy requirement of a child with CKD is assumed to be the same as for a healthy child. 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]. Providing sufficient energy and protein for growth whilst managing biochemistry can be a challenge. A large proportion of children with CKD require tube feeding in order to meet their nutritional requirements[3].

Renastep has been designed with a higher energy content (2kcal/ml) compared to standard paediatric enteral feeds. A comparison is shown in table 1 with standard paediatric enteral feeds. The higher energy content of Renastep allows for more energy to be given in a smaller volume, if required. This may support compliance with fluid restrictions.

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 effect of protein restriction on the progression of CKD has been studied in both the paediatric and adult population. A systematic Cochrane review of two studies exploring the relationship between protein intake and disease progression found that a low protein diet does not delay the progression to end stage kidney failure (CKD stage 5)[4]. However, protein intake may need to be reduced in those with persistently raised urea levels (>20mmol/L)[3]. Whilst there is no evidence for protein restriction having a nephroprotective effect, the evidence suggests that protein intake can be safely reduced to 0.98-1.1g/kg/day[5]. Protein intakes of >3g/kg per day should be avoided due to the associated phosphorus intake. The KDOQI guidelines recommendation regarding protein assumes adequate energy is also achieved[1].

Based on this evidence, Renastep has been formulated with 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 renal function. This is to ensure that the feed prescription can be individualised to the patients age and stage of CKD.

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]	99	1.5	1.5
Standard paediatric enteral feed[2]	100	2.8	2.8
Energy dense paediatric enteral feed[3]	150	4.1	2.8
Whole cow's milk[4]	63	3.4	5.4

* Renastart is a high energy powdered formula with low levels of electrolytes and vitamin A for the dietary management of renal failure from birth to 10 years.

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
3. Source: Average of 2 Energy dense paediatric enteral feeds (1.5kcal/ml) widely available in the UK, calculated from manufacturers data.
4. McCance and Widdowson's The Composition of Foods (2015) seventh summary edition. Cambridge: Royal Society of Chemistry.

Potassium

The KDOQI guidelines recommend that potassium should be restricted in children with CKD stages 2-5 who have or who are at risk of hyperkalemia[1]. Extracellular potassium influences muscle function and hypokalemia or hyperkalemia can cause fatal cardiac arrhythmias[6].

Due to the risk of cardiac arrest, the control of plasma potassium is a critical part of the dietary management of CKD. The KDOQI guidelines recommend a restriction of 1-3 mmol/kg/day as a starting point for young children[1].

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

Renastep may be used alone for short periods of time to decrease a very high plasma potassium level to within the normal hospital reference 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 plasma potassium levels within the local reference range.

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]	23/0.6
Standard paediatric enteral feed[2]	110/2.8
Energy dense paediatric enteral feed[3]	100/2.5
Whole cow's milk[4]	249/6.4

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
3. Source: Average of 2 Energy dense paediatric enteral feeds (1.5kcal/ml) widely available in the UK, calculated from manufacturers data.
4. McCance and Widdowson's The Composition of Foods (2015) seventh summary edition. Cambridge: Royal Society of Chemistry.

Renastep has been formulated with a lower level of potassium compared to standard paediatric oral and enteral tube feeds 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 guidelines, whilst providing sufficient energy and protein. Using a feed which is low in potassium can also enable a more liberal oral diet to be consumed. This could enable experiences around food and mealtimes to be more positive which is important in this patient group[7].

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[3]. Even when the serum phosphate level is within the normal range, dietary phosphate load is a key factor in the severity of hyperparathyroidism. There is emerging evidence to reduce dietary phosphate intake in CKD even before serum phosphate levels rise[7, 8].

The management of CKD-MBD is a combination of limiting dietary phosphate intake and using phosphate binders. Depending on the serum phosphate and parathyroid hormone (PTH) level, the KDOQI guidelines suggest restriction of dietary phosphate to 100% of the dietary reference intakes (DRI) for age in children with CKD stage 3-5 with a serum PTH above target and normal serum phosphate levels. In children with a high PTH and high serum phosphate, it is recommended that intake be restricted to 80% of the DRI[1].

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

Rees and Shaw (2007)[9] suggested the following practice guidelines for dietary phosphate intakes which are used in the UK.

Age	Dietary phosphate intake
Infants < 10 kg	< 400 mg daily
Children 10-20 kg	< 600 mg daily
Children 20-40kg	<800 mg daily
Children > 40 kg	< 1000 mg daily

Renastep has been formulated with a lower level of phosphorus compared to standard paediatric enteral feeds as shown in table 3. When taken at 100% of energy requirements, Renastep provides an intake of phosphorus which is below the suggested level thus supporting dietary phosphate restrictions.

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]. 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 first line phosphate binder in children is calcium carbonate[3].

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].

Table 3: 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]	18.4/0.6	23/0.6
Standard paediatric enteral feed (1kcal/ml)[2]	50/1.6	60/1.5
Energy dense paediatric enteral feed (1.5kcal/ml)[3]	51/1.7	58/1.5
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: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
3. Source: Average of 2 Energy dense paediatric enteral feeds (1.5kcal/ml) widely available in the UK, calculated from manufacturers data.
4. McCance and Widdowson's The Composition of Foods (2015) seventh summary edition. Cambridge: Royal Society of Chemistry.

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[1].

Renastep has been formulated to be lower in sodium than standard paediatric enteral feeds per 100kcal as shown in table 4.

Table 4: 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
Standard paediatric enteral feed[2]	60/2.6
Energy dense paediatric enteral feed[3]	50/2.1
Whole cow's milk[4]	67/2.9

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
3. Source: Average of 2 Energy dense paediatric enteral feeds (1.5kcal/ml) widely available in the UK, calculated from manufacturers data.
4. McCance and Widdowson's The Composition of Foods (2015) seventh summary edition. Cambridge: Royal Society of Chemistry.

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 5.

Table 5. 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]	41
Energy dense paediatric enteral feed[3]	53
Whole cow's milk[4]	61

1. Renastart 20% dilution: 20g Renastart made up to 100ml with water.
2. Source: Average of 2 standard paediatric enteral feeds (1kcal/ml) widely available in the UK, calculated from manufacturers data.
3. Source: Average of 2 Energy dense paediatric enteral feeds (1.5kcal/ml) widely available in the UK, calculated from manufacturers data.
4. McCance and Widdowson's The Composition of Foods (2015) seventh summary edition. Cambridge: Royal Society of Chemistry.

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 has been 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.

Flavour / Acceptability

Encouraging positive oral experiences and oral diet is key in children with kidney disease[14]. Children with CKD often experience taste changes, a poor appetite and poor oral intake[2, 15].

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[16].

Renastep can be used flexibly:

As a tube feed:

- To replace standard enteral feed (for a short period) if hyperkalemia is present or used in combination with standard enteral feed to reduce potassium intake.
- As a sole enteral feed alongside an unrestricted oral dietary intake to promote oral positive feeding experiences where dietary phosphate and or potassium restrictions are in place.
- In combination with a standard enteral feed to provide full enteral nutrition where dietary phosphate and/or potassium restrictions are in place.

As an oral supplement:

- When additional energy and protein are needed and dietary potassium and / or dietary phosphate restrictions are in place.
- In small volumes as a 'top up' to energy and protein intake or in times of illness as a meal replacement.
- As a 'mikshake style' drink to provide additional energy and protein when dietary potassium and / or dietary phosphate restrictions are in place.
- Mixed into foods and drinks to boost nutritional intake.

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Important notice: Renastep 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.

Renastep 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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