Renastart™

Practical guide for the use of Renastart™ in pediatric kidney disease

Supporting education in the
dietary management of rare diseases

Disclaimer

This practical guide should be **read in conjunction with national guidelines**, such as the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) pediatric nutrition guideline for the nutritional management of pediatric Chronic Kidney Disease (CKD).[1]

For use by Healthcare Professionals (HCP) only.

Not for use by parents of children with CKD or for individuals with CKD.

For general information only and must not be used as a substitute for professional medical advice or treatment.

All product information was obtained from manufacturer's information available as of the date of publication and is subject to change.

For specific product information, please consult the manufacturer.

Renastart is for use under medical supervision.

Renastart is a powdered formula of whey protein, carbohydrate, fat, vitamins and minerals for a diet restricted in protein, potassium, chloride, phosphorus, calcium and vitamin A. For use in the dietary management of pediatric kidney disease from 1 year of age.

Renastart is not intended to be a sole source of nutrition. It is formulated for use in conjunction with a secondary formula product and/or an oral diet.

A HCP must assess individual nutrient requirements and how Renastart may be used with a secondary source of nutrition to meet individual dietary intake goals.

Allergies/intolerances

Renastart is a cows' milk protein-based formula and is contraindicated for use in children with cows' milk protein allergy. It may not be suitable for children who have a cows' milk protein intolerance.

Foreward

Balancing the challenges of growth, electrolyte management, gastrointestinal complications, and individual nutrient needs based on primary renal disease are all challenges of pediatric CKD.[1] Especially for the young child, optimizing growth is critical as growth in the first three years has a significant impact on final adult height and neurocognitive development.[2] Metabolic, electrolyte and fluid abnormalities contribute to neurocognitive development, growth impairment, cardiac anomalies and/or bone damage, increasing morbidity and mortality risk.[1,3,4] There is no single ideal enteral product for pediatric CKD. Primary kidney disease may greatly influence biochemical markers and due to other possible complications of CKD, children have very individualized nutrition needs.

Renastart is a key tool for personalizing the feeding of a child with CKD to meet individual nutrition needs. Renastart is formulated to mix with other enteral products to create a nutritional profile specifically tailored to the individual child, or as a supplement to oral feeding. The powder formulation allows both for the concentration of the feed in children who are fluid restricted, or a less dense feed for children who may have gastrointestinal concerns at higher caloric densities. As a 98% whey-based formula, it is typically well tolerated and easily digested and its mild taste may support oral intake. Restricted in key electrolytes and nutrients, it can assist in titrating the feeding prescription to reflect biochemical values.

Well known for its work in rare inherited metabolic diseases, Vitaflo® is innovating nutritional products for pediatric kidney patients. The use of Renastart is well established within the European HCP community and becoming a valuable clinical tool in the United States. Vitaflo® is investing in the pediatric renal nutrition community with educational resources and research to bring the best patient care resources to clinicians working with children with CKD.

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Abbreviations

ARA	Arachidonic acid
ACE inhibitor	Angiotensin-converting enzyme inhibitor (for blood pressure management)
AKI	Acute Kidney Injury
BUN	Blood Urea Nitrogen
CKD	Chronic Kidney Disease
Ca	Calcium
CO2	Serum bicarbonate
Cr	Creatinine
DHA	Docosahexaenoic acid
DRI	Dietary Reference Intake
HCP	Healthcare Professional
HD	Hemodialysis
H	High
K	Potassium
KDOQI	Kidney Disease Outcomes Quality Initiative
LCP	Long-chain polyunsaturated fatty acids
L	Low
Na	Sodium
NKF	National Kidney Foundation
PD	Peritoneal dialysis
PO4	Phosphorus
WNL	Within normal limits

Collaborators

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Contents

1.0 What is Renastart?

Renastart™ is the only pediatric renal-specific formula designed to address the evolving challenges in the dietary management needs of children throughout the spectrum of CKD. It is a powdered formula containing whey protein, carbohydrate, fat, vitamins and minerals for a diet restricted in protein, potassium, chloride, phosphorus, calcium and vitamin A.

2.0 Indications for Use

Renastart is indicated for the dietary management of pediatric kidney disease from 1 year of age. The capacity of its use within a renal diet prescription should be determined by a medical professional such as a pediatric renal dietitian or nephrologist.

Renastart is formulated for use as a supplement to an oral diet or in combination with another enteral formula to achieve appropriate levels of renal specific nutrients of concern. Nutrition needs for the pediatric renal patient are complex and varied throughout the spectrum of CKD due to factors such as primary kidney disease, biochemical markers, and growth. Tailoring the enteral feeding regimen to the individual is an important aspect of medical nutrition therapy.

3.0 Overview of Clinical Use

Formula Modulation	Restricted in renal specific nutrients of concern, Renastart can easily be mixed with other formulas to modulate the feed to the unique nutritional needs of the individual. Renastart can be concentrated up to 2 kcal/ml to meet varying nutrition and fluid needs: • A lower calorie concentration may be necessary for the child with gastrointestinal intolerance at higher caloric density.[5] • A higher calorie concentration may be necessary if fluid restriction is indicated.[1]
Oral Supplementation	Supporting oral motor skills and encouraging positive eating experiences for children on restrictive diets is an important component of dietary management.[6] The mild unflavored taste of Renastart and its nutritional profile make it a suitable oral supplement allowing greater flexibility with diet restrictions, which may help with common feeding challenges in children with CKD.[6]
Dietary Management of Hyperkalemia	The restricted potassium content of Renastart provides an alternative option to manage potassium dietary intake and flexibility in the use of complementary foods: • May be used as a short term sole source of nutrition for acutely elevated serum potassium. • May support variety in the diet and inclusion of nutritious potassium containing foods (e.g. fruits) which may otherwise be restricted.
Dietary Management of Acute Kidney Injury (AKI)	Provides more options in the dietary management of AKI and related electrolyte abnormalities. This includes the possibility of avoiding dialysis as elevated serum potassium is a common indication for the need for dialysis.[7]
Dietary Management of Acidosis	Acidosis is a common complication of CKD, impairing growth and accelerating the progression of CKD.[1] Renastart's restricted chloride content can support the dietary management in case of acidosis which may reduce the need for additional interventions to control serum bicarbonate.

4.0 Clinical Features and Benefits

Potassium

Elevated serum potassium levels are common in children with CKD and may be related to potassium retention due to original kidney disease, acidosis, medication use, tissue or cell breakdown, constipation and more.[9] Hyperkalemia is defined as a blood potassium (K) level above the normal reference range of 3.5–5 mEq/L.* Issues such as a hemolyzed blood sample, or secondary causes of hyperkalemia should be considered and addressed before Renastart is initiated. If these secondary causes of hyperkalemia cannot be adjusted, Renastart can be a helpful tool for the dietary management of hyperkalemia.[9]

Table A — Dietary management of secondary causes of hyperkalemia with Renastart

An alternative method for potassium management[9]	Clinical practice often requires modification to the potassium levels of formula to control K intake. Publications highlight concerns with a commonly used method to control potassium intake, due to undesirable alteration of other nutrient levels (e.g. increase in sodium and aluminum and decrease in calcium), and serum electrolyte derangements (e.g. severe hypokalemia and hypocalcemia).[10–14] Use of Renastart as a short-term sole source of nutrition may be an effective dietary intervention to bring an acutely elevated K level within normal reference range. Use of Renastart long-term in combination with another formula or an oral diet may support the reduction of overall dietary potassium intake.
Provides flexibility and choice	Renastart can be combined with another enteral product of choice to achieve potassium intake tailored to the individual needs of each patient.
If an ACE inhibitor is needed to control blood pressure	Renastart allows more flexibility with the use of the ACE inhibitor, by modulating the diet to manage the side effect of hyperkalemia.[13]
Flexibility as a restricted potassium oral supplement	Oral stimulation and food introduction are important for physiological goals in the setting of a restricted therapeutic diet.[6] Renastart use supports flexibility in advancement of oral diet, which allows a wider range of food choices, while also supporting energy requirements in children with poor appetite.[15]

* Local hospital and laboratory reference ranges may vary and age-related ranges may apply.

Chloride

Acidosis is a common complication of CKD and AKI.

Children with serum bicarbonate levels <18 mEq/L have poor growth and progress faster to end stage renal disease.[10] KDOQI guidelines recommend children with CKD maintain a CO2 level >22 mEq/L.[1]

Renastart's restricted chloride content may support the dietary management of patients with acidosis.

Sodium

Children with CKD with renal tubular disorders have impaired ion exchange, including fluid and salt wasting.[1] Depressed serum sodium levels have implications for growth and neurological outcomes.[1,15–17]

Renastart use may reduce the need for additional sodium based supplements.

Vitamin A

Elevated serum retinol levels have been associated with hypercalcemia and increased osteoclastic action, regardless of dietary calcium intake. Calcium release from bone may be a risk factor for cardiovascular complications.[18] 77% of children stages 2–5 CKD and 94% of children on dialysis have elevated serum retinol levels.[18–19] Those receiving enteral formula are more likely to have elevated retinol levels.[18]

The restricted vitamin A content of Renastart may help reduce the overall dietary intake of vitamin A in children with CKD.

Phosphorus

High dietary phosphorus intake is a well-known risk factor to manage in bone mineral density disorders in CKD.[1] KDOQI guidelines recommend children with elevated PTH levels limit phosphorus intake to the DRI and children who additionally have elevated serum phosphorus levels be restricted to 80% of the DRI.[1]

More recently, Clinical Practice Recommendations (CPRs) from the Pediatric Renal Nutrition Taskforce (PRNT) advise limiting phosphorus to the Suggested Dietary Intake (SDI) reflecting an international range of appropriate values, noting that with hyperphosphatemia, an intake toward the lower end of the SDI would be most appropriate.[20]

The oral solid diet of children with CKD commonly exceeds recommendations for phosphorus intake and Renastart may be a helpful tool to reduce dietary phosphorus intake.[21]

The restricted phosphorus content of Renastart allows for reduction in overall dietary phosphorus intake and may support greater flexibility in oral diet advancement.

Calcium

KDOQI guidelines recommend calcium intake for children with CKD be within 100–200% of the DRI for age. The PRNT CPRs indicate an intake of 100–200% of the SDI, with the inclusion of both diet and calcium based medications.[20] Children with CKD may consume calcium-based phosphorus binders and may be at risk for excessive total calcium intake.[1, 20]

Provision of additional calcium is clinically more practical than removal of excess calcium, therefore the restricted calcium content of Renastart allows for modulation of calcium intake.

Protein

Total protein needs relative to total energy needs may be low in young children with CKD who are usually smaller in size.

KDOQI makes the following recommendations for protein intake[1]:

- 100% to 140% of DRI for age for children with CKD stage 3, and 100% to 120% for children with CKD stage 4–5. Higher levels may result in increased blood urea nitrogen.
- Recommendations for children and adolescents on hemodialysis are DRI plus 0.1 g/kg/day.
- Recommendations for children and adolescents on peritoneal dialysis are DRI plus 0.15 g/kg/day to 0.3g/kg/day.

The PRNT CPRs advise an intake within the SDI, noting that those with high urea levels (BUN) may need closer to the lower end of the SDI.[22]

These recommendations are much lower than those previously given because there is a lack of evidence that high protein intake on dialysis is beneficial and, in fact, may be detrimental.[1] To limit

young children, especially those with CKD not yet on dialysis, to DRI for protein as recommended by KDOQI and PRNT, a restricted protein content may may support dietary intake goals.[1, 22]

The restricted protein content of Renastart allows flexibility with other dietary protein sources to facilitate the provision of adequate intake. It can be mixed with other formulas and supplements to meet the varying protein requirements of children with CKD.

DHA

Data on DHA intake in the pediatric renal population is lacking, however adults on dialysis therapy consume fish in amounts far less than recommendations.[23]

Renastart is formulated with a source of pre-formed DHA which may support dietary intake in a group of patients whose diet is likely deficient in DHA.

The overall fatty acid composition of Renastart includes DHA, ARA, Linoleic and Alpha-linolenic acid.

5.0 Additional Benefits of Renastart

Magnesium

Higher serum magnesium levels in patients on peritoneal dialysis receiving enteral formula have been reported.[24, 25]

The restricted level of magnesium in Renastart may support adequate intakes based on serum levels in children on peritoneal dialysis.

Aluminum

It is well established that children with CKD may be at risk for lifetime aluminum accumulation. There are significant neurological and bone consequences related to aluminum exposure.

With the exception of breast milk, whey-based formulas are known to be the lowest in aluminum content[26] compared to casein-based, soy-based and hydrolyzed formulas. Renastart is 98% whey-based.

Gastric emptying

Whey-based formulas are associated with improved gastric emptying and children with CKD are at risk for delayed gastric emptying.[5]

6.0 Examples of Renastart in Use

Clinical Scenario	Nutrition Intervention	Considerations
Elevated serum potassium in AKI	Provide as a supplement to oral diet or mixed with another enteral product.	If renal replacement therapy is started, potassium may need to be liberalized.[7]
Acutely elevated serum potassium level	Provide as a short-term sole source of nutrition.	Monitor electrolytes closely and discontinue Renastart as sole source of nutrition when serum potassium level is in normal reference range. Consider chronic potassium management needs.
Child with stage 4 CKD, on ACE inhibitor with elevated serum potassium level[9]	Renastart can be added or increased to replace part of current formula. Total potassium content of formula mixture decreases and ACE inhibitor may be continued.	Monitor electrolytes closely: • May need further potassium restriction if CKD worsens. • May be able to liberalize potassium restriction if dialysis is started.
Child with hypercalcemia despite less than DRI calcium intake. Serum retinol levels evaluated and elevated[17]	Add in combination with current enteral product to support a lower total Vitamin A dietary intake.	Evaluate other electrolyte needs to determine appropriate ratio of enteral products.

7.0 Case Study* Series Outlining Uses of Renastart

Background

A 13 month old male child with stage 3 CKD, secondary to posterior urethral valves.

Anthropometrics	
Weight	8.6 kg (5–10%ile)
Length	75.6 cm (25%ile)
Weight/length	10%ile
Head circumference	45.9 cm (25–50%ile)

Biochemistry	
K	5.9 mEq/L (mildly elevated)
CO2	19 mEq/L (mildly depressed)
BUN	37 mg/dL (H)
Cr	0.8 mg/dL (H)
Ca	9.7 mg/dL (WNL)
PO4	4.9 mg/dL (WNL)

Dietary Intake

The child has been receiving a standard infant formula ad lib in addition to an oral solid food diet. Parents report that the child is taking some baby food but having difficulty advancing texture. Solid food and formula intake have not increased much in the past 2–3 months. Dietary assessment estimates solid food and formula intake of approximately 100 kcal/day and 500 kcal/day, respectively. Estimated energy needs are 685 kcal/day and 9.5 grams of protein/day.

*All case studies are fictitious.

Problems

Mildly depressed CO2, mildly elevated potassium, and inadequate caloric intake.

Intervention

Add 30 kcal/fl oz Renastart at a ratio of 1/4 Renastart to 3/4 standard infant formula.

Outcomes

1. Base formula **calorie content increased** from 20 kcal/fl oz to 22.5 kcal/fl oz.
2. Per 100 kcal, **reduction in potassium and chloride** content, from 110 mg to 77 mg and 68 mg to 49 mg, respectively.

The child is now 16 months of age, presenting at clinic with a rapid change in GFR and has advanced to stage 4 CKD. Parents report that oral intake increased with addition of Renastart at the last clinic visit. The child has made only limited progress with additional solid food. **Weight has increased.**

Anthropometrics	
Weight	9.4 kg (10–25%ile)
Length	78 cm (10–25%ile)
Weight/length	10–25%ile
Head circumference	46.1 cm (25–50%ile)

Biochemistry	
K	7.4 mEq/L (H)
CO2	22 mEq/L (WNL)
BUN	78 mg/dL (H)
Cr	1.4 mg/dL (H)
Ca	9.5 mg/dL (WNL)
PO4	5.0 mg/dL (WNL)
Na	130 mEq/L (L)

Problems

Critically high serum potassium, mildly depressed serum sodium, greatly elevated BUN.

Intervention

Offer 30 kcal/fl oz Renastart for short term use as sole source nutrition. Bring patient back in 24–48 hours to reassess serum potassium. When potassium returns to normal serum levels, continue with 1/3 Renastart to 2/3 standard infant formula. Continue to monitor potassium closely and adjust Renastart/ standard infant formula ratio as needed.

Outcomes

1. Per 100 kcal, **potassium is temporarily reduced** from 77 mg to 19 mg.
2. Once serum potassium in normal reference range, **formula ratio changed** to 1/3 Renastart to 2/3 standard infant formula, maintaining potassium content at 67 mg.
3. Sodium per 100 kcal is temporarily increased to 41 mg from 31 mg and is maintained at 32 mg.
4. Protein per 100 kcal is temporarily decreased to 1.6 g from 2 g and maintained at 1.9 g.

The child is now 2 years and 4-months old and has been on PD for 3 months. A supplemental nocturnal tube feeding via gastrostomy tube (g-tube) was started 2 months prior to starting dialysis to compenstate for declining intake and inadequate weight gain. He has some urine output. A protein modular has been added to the formula mixture to increase protein intake to account for dialysis losses. Parents report the child is now starting to eat a little bit better and the family is anxious to increase oral diet but feel that the tube feeding makes him feel full.

Anthropometrics	
Weight	12.4 kg (25–50%ile)
Height	85.4 cm (10–25%ile)
BMI	17 kg/m^2 (50–75%ile)
Caloric assessment	
Caloric assessment	1024 kcal
Calories from oral solid food	~500
Calories from nocturnal feeds	450
Calories from oral formula	~100–150

Biochemistry	
K	5.0 mEq/L (WNL)
CO2	24 mEq/L (WNL)
BUN	45 mg/dL (H)
Cr	3.3 mg/dL (H)
Ca	9.7 mg/dL (WNL)
PO4	5.5 mg/dL (WNL)

Problems

Family would like to increase solid food but child feels full.

Serum potassium and phosphorus are trending up, likely due to greater intake of solid food.

Intervention

Discontinue nocturnal tube feeding. Offer 30 kcal/fl oz Renastart after meals and snacks daily. A goal of 12 fl oz of Renastart (360 kcal) is set to allow a calorie deficit to encourage increased oral food intake. If the child is unable to meet 12 fl oz goal, remainder can be given via tube. As oral solid food intake increases, supplemental Renastart can be further reduced, as assessed at regular clinic visits by the dietitian.

Outcomes

1. The mild taste of Renastart supports **flexibility for use as an oral supplement.**
2. The child is willing to consume all prescribed Renastart while **advancing oral diet.**
3. Renastart can be **concentrated as needed to meet varying energy requirements,** supporting volume allowance for solids.
4. The **restricted potassium and phosphorus content of Renastart supports variety in solid food intake** and the overall oral diet for the child.

8.0 Appendix

Table B

Information on select renal specific nutrients per 100 kcal

Per 100 kcal	Renastart**[27]	Breastmilk, mature term*[28, 29]	Whole cows' milk[28, 29]
Protein (g)	1.5	1.5	5.1
Sodium (mg)	42	24	70
Potassium (mg)	19	73	216
Chloride (mg)	16	30*	144*
Phosphorus (mg)	17	20	138
Calcium (mg)	20	46	185
Magnesium (mg)	7	4	16
Vitamin A (µg RE)	22	87	75

Per 100 kcal	Renastart**[27]	Standard infant formula[30]	Infant renal formula[31]	Adult pre-dialysis formula[32]
Protein (g)	1.5	2.1	2.2	2.5
Sodium (mg)	42	25	24	45
Potassium (mg)	19	110	80	59
Chloride (mg)	16	49	59	52
Phosphorus (mg)	17	44	28	40
Calcium (mg)	20	82	56	59
Magnesium (mg)	7	6	6	9
Vitamin A (µg RE)	22	90	61	53

* Numbers are approximate, extrapolated from other data and may vary based on specimen.[23]

**Renastart is not a breast milk substitute and is indicated from 1 year of age.

Table C

Information on Renastart at various concentrations per 100 ml

Per 100 ml	Renastart 1 kcal/ml[27]	Renastart 1.5 kcal/ml[27]	Renastart 2 kcal/ml[27]	Infant renal formula* 0.67 kcal/ml[31]
Calories (kcal)	100	150	200	67
Protein (g)	1.5	2.3	3	1.5
Sodium (mg)	42	63	84	16
Potassium (mg)	19	29	38	54
Phosphorus (mg)	17	25	33	19
Calcium (mg)	20	30	40	38
Magnesium (mg)	7	11	14	4
Vitamin A (µg RE)	22	33	44	203

Per 100 ml	Renastart 1 kcal/ml[27]	Renastart 1.5 kcal/ml[27]	Renastart 2 kcal/ml[27]	Adult pre-dialysis formula* 1.8 kcal/ml[32]
Calories (kcal)	100	150	200	180
Protein (g)	1.5	2.3	3	4.5
Sodium (mg)	42	63	84	80
Potassium (mg)	19	29	38	105
Phosphorus (mg)	17	25	33	72
Calcium (mg)	20	30	40	106
Magnesium (mg)	7	11	14	17
Vitamin A (µg RE)	22	33	44	95

* Standard dilution.

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