



A practical guide to the use of **PKU trio™** in young children  
with phenylketonuria (PKU)



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Supporting education in the  
dietary management of rare diseases

## Disclaimer

This practical guide is for use to support the transition to **PKU trio™**. This practical guide should be read in conjunction with local guidelines for the dietary management of phenylketonuria (PKU). It is based on American and European guidelines for the management of PKU as well as clinical experience and best practice recommendations for the management of PKU in paediatrics<sup>(1-3)</sup>.

The guide is only for use by health care professionals working with patients with PKU.

This practical guide is **not** for use by patients with PKU or their families/caregivers.

The practical guide is for general information only and must not be used as a substitute for professional medical advice.

The product information contained within this guide, although accurate at the time of publication, is subject to change.

The most current product information may be obtained by referring to product labels.

### Important notice

**PKU trio** is a medical food intended for use under medical supervision

**PKU trio** must only be consumed by people with proven PKU under strict medical supervision.

Suitable from 1 year of age.

Diet must be supplemented with natural protein, water and other nutrients in prescribed quantities to supply the phenylalanine (phe), fluid and general nutrition requirements.

**PKU trio** can be used in pregnancy.

Not for use as a sole source of nutrition.

Not for intravenous use.

Any unused portions should be refrigerated and consumed within 24 hours.

## Collaborator

VitaFlo® dietitians in collaboration with **Jessica Burfield**, RD, CSP, LDN, Metabolic Dietitian, Children's Hospital of Philadelphia.

## Abbreviations

<b>DHA</b>	Docosahexaenoic Acid	<b>fl.oz</b>	Fluid ounces
<b>phe</b>	Phenylalanine	<b>g</b>	Grams
<b>PKU</b>	Phenylketonuria	<b>mg</b>	Milligrams
<b>PE</b>	Protein equivalent	<b>ml</b>	Millilitres
<b>phe-free</b>	Phenylalanine-free		

### Overview

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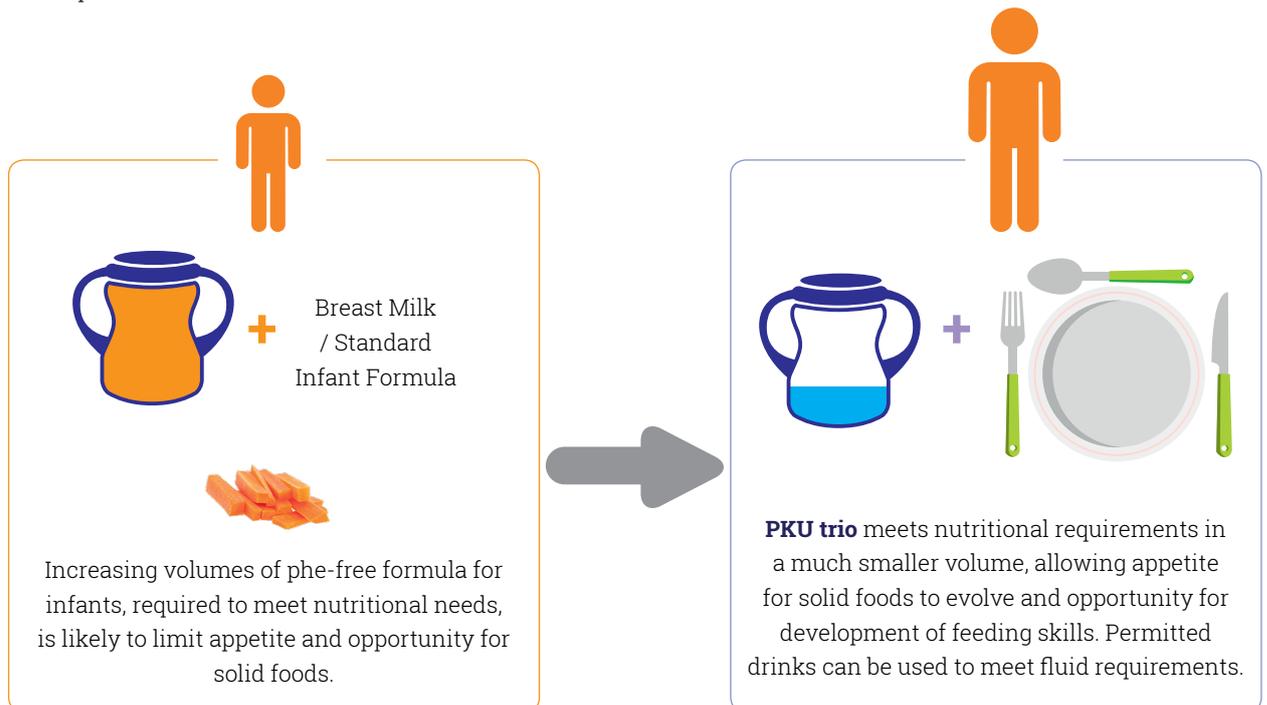
## Overview

Early childhood is a particularly difficult time to manage phenylketonuria (PKU) for several reasons. Compared to later in life, phenylalanine (phe) tolerance is more likely to be variable due to the influence of growth. Target ranges of serum phe (120-360 $\mu$ mol/L<sup>(1-3)</sup>) must be maintained and so the diet may require frequent manipulation. Added to this, children are exploring different tastes and textures and displaying neophobic responses to food which are expected aspects of their development.

Despite these challenges, a child with PKU can be given the same opportunities for food experience and development as any other child. A variety of tastes and textures (within the protein restriction) should be offered throughout this time to allow development of feeding skills such as tongue control, biting, chewing, self-feeding and social aspects of mealtimes.

As part of this development, solid food begins to replace fluid intake, whether it is breastfeeds, standard formula or phe-free formula for infants. To meet increasing protein requirements, high volumes of formula may be required or formula may need to be concentrated. Both scenarios present problems to feeding development and tolerance. Avoiding large volumes of formula, whilst still meeting protein requirements for growth, encourages an appetite for establishing healthy and age-appropriate eating behaviours.

**PKU trio** is designed to be a protein substitute that supplies the same protein equivalent (PE) as a phe-free formula for infants in a lower volume to facilitate appropriate feeding development. This is achieved by a more concentrated presentation with no compromise in nutritional value, so that a child can progress with intake of solid foods and develop a more food-based diet.



 = Phe-free formula for infants

 = **PKU trio**

Non-protein energy sources (fat and carbohydrate) in **PKU trio** help meet the demands of growth in a simple format that is easy to use. Once established, **PKU trio** can be continued life-long and is flexible in preparation to meet requirements and preferences throughout the life stages.

Although **PKU trio** is a life-long product, this practical guide explains how **PKU trio** is introduced into the diets of young children from 1 year of age requiring a medical food that provides phe-free PE and non-protein energy sources.

## 1.0

## **An introduction to PKU trio**

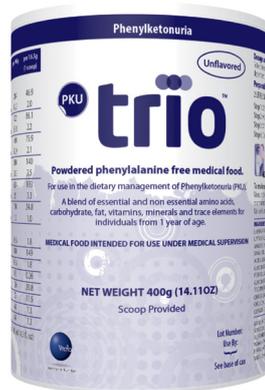
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- 1.1 What is PKU trio?
- 1.2 Who is PKU trio for?
- 1.3 Nutritional information
- 1.4 Why use PKU trio?
- 1.5 Features of PKU trio

## 1.1 What is PKU trio?

**PKU trio** is:

- For use in the dietary management of PKU
- A powdered phenylalanine free\* medical food containing a blend of essential and non-essential amino acids, carbohydrate, fat, vitamins, minerals and trace elements
- Available in flavoured and unflavoured options



\* No added phe. Phe may be present in trace amounts from other ingredients (<10mg/100g powder; <3mg/100ml reconstituted product when prepared to standard dilution according to manufacturer's instructions).

## 1.2 Who is PKU trio for?

**PKU trio** can be used:

- Throughout childhood from 1 year of age and adolescence
- Throughout adulthood including pregnancy and lactation
- For individuals returning to diet
- By individuals in the above groups experiencing taste fatigue or non-adherence with their current formula
- For individuals who prefer a milder flavour or powdered presentation

Once established, **PKU trio** can continue throughout the life stages without the need to change product.

**This practical guide will focus on the transition from the current phe-free formula to PKU trio in children around 1 year of age. However, the transition from an alternative protein substitute to PKU trio can be made at any stage throughout life.**



**An online calculator, available at [www.Vitaflo-VIA.com](http://www.Vitaflo-VIA.com) is a tool to develop a bespoke transition plan for any age.**

### 1.3 Nutritional information

**PKU trio** provides 405kcal and 30g PE per 100g of powder. It contains essential and non-essential amino acids, carbohydrate, fat, vitamins, minerals and trace elements to bridge nutritional deficits caused by protein restriction in the diet.

	Per 100g	Per 1 scoop (16.5g)	Per 10g PE*
Energy (kcal)	405	67	134
Protein equivalent (g)	30	5	10
Fat (g)	14.3	2.4	4.8
saturates (g)	1.5	0.25	0.5
monounsaturates (g)	8.9	1.5	3
polyunsaturates (g)	3.3	0.54	1.08
Docosahexaenoic acid (DHA) (mg)	200	33	66
Carbohydrate (g)	38.9	6.4	12.8
Vitamin D (µg)	15	2.5	5
Tyrosine (g)	2.98	0.49	0.98
Calcium (mg)	850	140	280

\* Equivalent to approximately 5 fl.oz/150ml when reconstituted at standard dilution (33g powder/2 scoops and 4 ½ fl.oz/135mls water giving a caloric density of 26kcal/fl.oz).

### 1.4 Why use PKU trio?

**PKU trio** provides a trio of macronutrients that is beneficial to specific scenarios where a higher energy formula is indicated, including:

- Early childhood where intake may be compromised by poor/fussy eating or where portion sizes are still small due to age or developmental stage
- Individuals that have an increased energy need
- Where there is either limited availability or poor adherence to specialised low protein foods and additional energy contribution from a medical food is beneficial.

## 1.5 Features of PKU trio

### Nutritional features of PKU trio

#### Amino acid profile tailored to PKU

- A phe-free source of amino acids supplemented with optimal levels of conditionally-essential tyrosine designed to meet recommendations for PKU (2800-3500mg/day 1-4 years<sup>(2,3)</sup>)



#### Non-protein energy source

- Energy derived from fat and carbohydrate ensures protein is fully utilised and not used as an energy source
- Meeting energy requirements is important for prevention of catabolism and maintaining metabolic control



#### Fat profile aligned with recommendations

- Complete fatty acid profile comprising the essential fatty acids, linoleic and  $\alpha$ -linolenic acid, and the long chain polyunsaturated fatty acid DHA, often deficient in a protein-restricted diet in children<sup>(4,5)</sup>
- A healthy profile of saturated and monounsaturated fats compliant with latest recommendations relating to chronic public health<sup>(6,7)</sup>



#### Source of micronutrients compromised by a protein-restricted diet

- Provides micronutrients otherwise consumed through dietary protein, such as calcium and vitamin D, which can be low in PKU diets<sup>(8)</sup>. Provision of these micronutrients from a protein substitute is beneficial to meeting requirements<sup>(9)</sup>
- The need to provide separate vitamin and mineral supplementation, which brings barriers to adherence, is reduced



### Practical features of PKU trio



#### A life-long product

- Once introduced around 1 year of age, PKU trio can be continued throughout subsequent life stages without the need to change product, complementing the management for life recommendation<sup>(1,3)</sup>



#### Low volume when reconstituted

- Meets energy requirements in a lower volume than phe-free formula for infants
- Avoids having to concentrate or fortify phe-free formula to meet requirements, reducing any potential intolerance



#### Easy preparation

- Enclosed scoop provides 5g PE so the required amount can be easily measured and mixed with water\*
- The scoop allows the product to be prepared easily with reduced user error

\* Refer to **Section 4.0 'Preparation Guidelines'** for further details.



#### Flexibility to prepare to different concentrations

- PKU trio can be taken at standard dilution (see **Section 4.0 'Preparation Guidelines'**) or concentrated if an individual would like to take an even lower volume drink. Additional water should be encouraged throughout the day to meet individual fluid requirements. See **Appendix 2** for osmolality at different concentrations



#### Vanilla and unflavoured options

- The unflavoured variety of PKU trio may help the transition from phe-free formula for infants
- Both options are useful when an individual is experiencing taste fatigue or non-adherence with their current medical food
- Both options can be flavoured or used in recipes\*

\* Recipe ideas are available upon request from your VitaFlo representative.

## 2.0 **Transitioning to PKU trio**

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- 2.1 **An overview of transitioning from a phe-free formula for infants to PKU trio**
- 2.2 **Step-by-step guide to transitioning from a phe-free formula for infants to PKU trio**

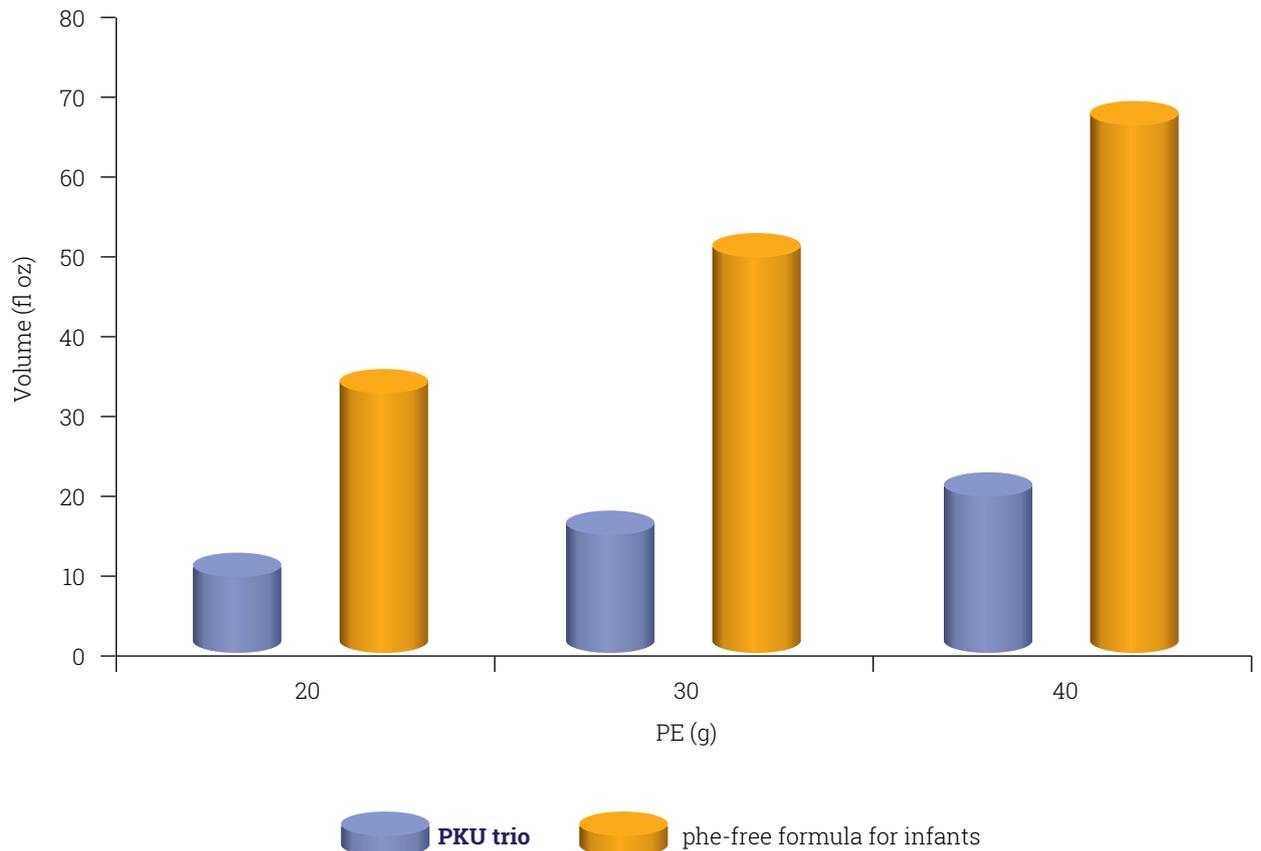
## 2.1 An overview of transitioning from a phe-free formula for infants to PKU trio

As a child reaches 1 year of age, nutritional requirements continue to increase to keep up with growth. A phe-free formula for infants becomes limiting in achieving requirements and may be concentrated or given in large volumes to meet demands. With either approach, problems can arise including:

- Intolerance associated with volume (e.g. reflux, vomiting)
- Intolerance associated with osmolality (e.g. constipation, loose stools)
- Reduced appetite for solid food and early satiety
- Delayed feeding skills due to limited intake of solids
- Inaccuracy and user error when concentrating or fortifying feeds

**PKU trio** avoids the need for large volumes or concentration of phe-free formula for infants by providing equivalent nutrition in a lower volume. Less volume and an age-appropriate nutritional profile allows appetite for solid food to evolve as well as healthy eating behaviours and development.

The graph below shows volumes of phe-free formula for infants\* and **PKU trio** required to meet a range of PE requirements:

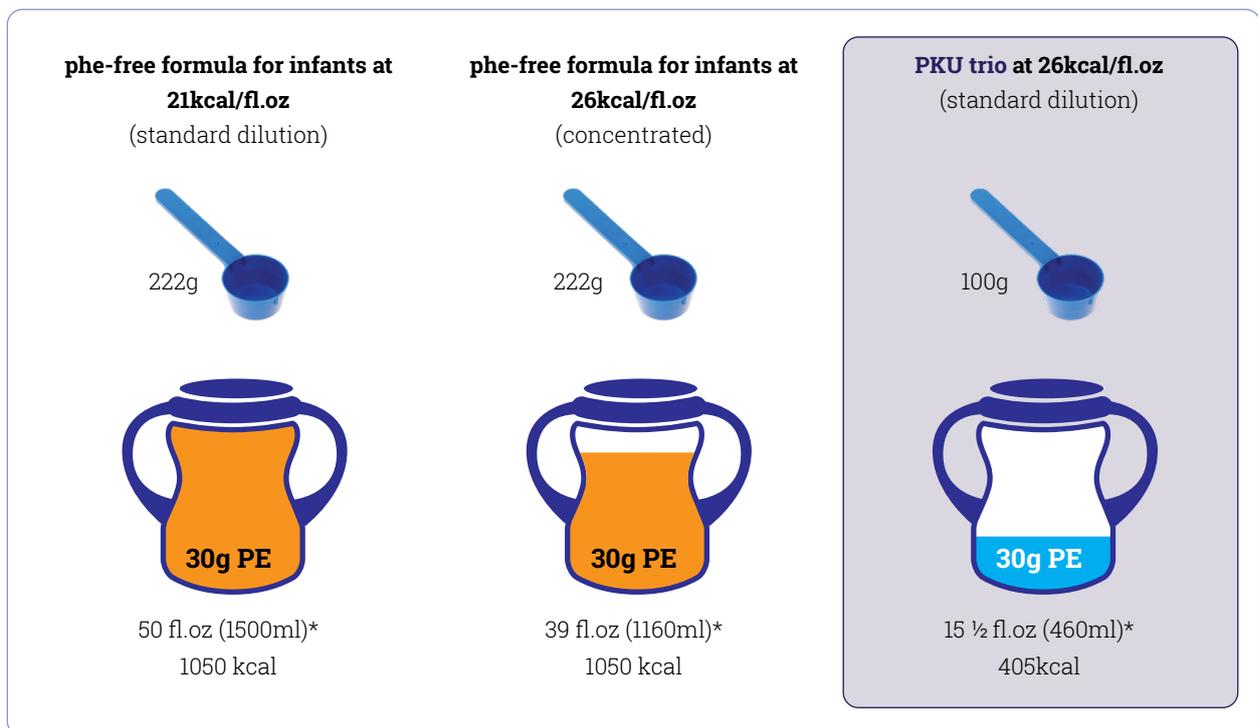


\* Values taken from products readily available in the USA.

**Example:**

1 year old boy with PKU

Total protein requirements <sup>(9)</sup>	35g/day
Energy requirements <sup>(9)</sup>	850kcal/day
phe tolerance	250mg/day (5g of natural protein)
PE requirements from a protein substitute	30g/day



The illustration above shows that the same PE can be achieved in a much smaller volume of **PKU trio** compared to phe-free formula for infants. This helps prevent the child becoming too full from fluid and encourages an appetite for a solid diet.

The above graphic is for illustrative purposes only and it is considered best practice to prepare individual servings of **PKU trio** separately at the time of consumption. Please refer to the product label for information regarding correct storage of reconstituted **PKU trio**.

\* Figures rounded.

## 2.2 Step-by-step guide to transitioning from a phe-free formula for infants to PKU trio

Transitioning from a phe-free formula for infants to **PKU trio** should be undertaken at a time and pace acceptable to the child and family. Children react individually to change and the transition may be more challenging in some children than others, requiring patience and persistence. Transition from any phe-free formula can be made in a similar way. Below is an example of the stages of transition to successfully establish **PKU trio** from a phe-free formula for infants. The example shows **PKU trio** being mixed with the current phe-free formula, however, the two protein substitutes can be given separately if desired.

Based on a 1 year old child receiving 5g natural protein/250mg phe and 30g PE from phe-free formula for infants.



An online calculator is available at [www.VitaFlo-VIA.com](http://www.VitaFlo-VIA.com) to transition your patient from the current phe-free formula to **PKU trio**. The calculator can be used to individualise transition plans with consideration of measurement method, desired concentration and number of transition steps.

Start	Stage 1 – initial introduction of PKU trio	Stage 2 – gradual build-up of PKU trio	Stage 3 – rearrange feeds to accommodate individual needs
PE provided entirely by phe-free formula for infants which may be concentrated or supplemented to meet nutritional requirements.	Start to replace phe-free formula for infants with <b>PKU trio</b> . Identify when the child is most cooperative and receptive and start with this feed first. Replace with the corresponding PE from <b>PKU trio</b> – see <b>Appendix 1</b> for corresponding volumes.	Continue to replace phe-free formula for infants with <b>PKU trio</b> at a pace tolerated by the child. Continue to do this until all feeds are replaced with <b>PKU trio</b> .	Feeds can eventually be rearranged to fit more easily in to family mealtimes and routine. This also creates time for other developmental activities and play.
5 feeds of phe-free formula for infants per day providing 30g PE per day.   x 5 feeds per day	For all feeds: <ul style="list-style-type: none"> <li>Reduce PE derived from the current phe-free formula for infants by a small amount e.g. 2g PE per feed</li> <li>Replace with the volume of <b>PKU trio</b> to provide the equivalent PE.</li> </ul>  x 5 feeds per day	For all feeds: <ul style="list-style-type: none"> <li>Continue to increase <b>PKU trio</b> and decrease the phe-free formula for infants by volumes equating to the same PE until all phe-free formula for infants has been replaced.</li> </ul>  x 5 feeds per day  x 5 feeds per day	A reduced overall volume allows fewer feeds throughout the day.   x 3 feeds per day  See ' <b>Section 3.0</b> ' for guidance on incorporating <b>PKU trio</b> into mealtimes and addressing difficult feeding behaviours.
Fluid requirement likely to be met by phe-free formula for infants.	Offer additional fluids after <b>PKU trio</b> and in between feeds to maintain fluid requirement.		

Continue to provide 5g natural protein/250mg phe per day. Increase protein-free and very low protein foods to increase energy derived from solid foods. Foods can be fortified with non-protein additions such as butter/oils to increase energy density of the diet if not enough energy can be derived from very low protein/protein-free foods.

Phe levels should be stable and within target range before introducing or increasing **PKU trio** and monitored throughout the transition period according to local/national policy.

 = Phe-free formula for infants  
 = **PKU trio**

**3.0**

## **Tips and troubleshooting for the use of PKU trio**

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**3.1 Feeding behaviour, tolerance and practicalities**

**3.2 Reducing volume further**

3.0

## 3.1 Tips and troubleshooting for the use of PKU trio

Outlined below are some practical reminders on how to encourage an easier transition and adherence to PKU trio.

Many of the principles for using PKU trio are the same as those that apply to general paediatric dietetic practice and feeding a young child. The tips below may be useful for discussion with families and carers.

### Feeding behaviour problems

Feeding behaviour problems are common in young children and are often heightened in children with PKU<sup>(3, 10, 11)</sup>. It is common for young children to refuse new tastes and this also applies to PKU trio. Taste preferences are typically learned between 4-14 months after which, rejection is more likely and so timely introduction of PKU trio at 1 year is beneficial.

- Aim to establish routine so a child knows when to expect both PKU trio and food, hence they do not become over-hungry and can anticipate mealtimes.
- Give PKU trio before meals to ensure the entire volume is taken. It can be helpful if everyone has a drink at mealtimes so that the child does not feel singled out.
- Present PKU trio and food positively and create a calm, enjoyable mealtime environment without distractions to reduce anxiety around the new medical food.
- Be firm and persistent, treating PKU trio with the same importance as if it is a medication. Children try new tastes several times before accepting a different food or formula.
- Make sure all family members and carers are consistent with feeding expectations so the child understands what is expected of them. The entire prescribed volume of PKU trio must be consumed with no leniency to ensure complete nutrition.
- Eating with other people encourages acceptance of food as children learn by copying. Set a good example by incorporating and sharing very low-protein and protein-free foods into the family diet.

### Tolerance

When transitioning from one medical food to another, it is normal that mild gastrointestinal changes, such as constipation or loose stools, may occur initially.

- If mild intolerance occurs, take a step back and slow the rate of transition until the issue resolves and then continue to progress as tolerated. The transition calculator for PKU trio can be found at [www.Vitaflo-VIA.com](http://www.Vitaflo-VIA.com) and [www.nestlehealthscience.us/vitaflo-usa](http://www.nestlehealthscience.us/vitaflo-usa) and helps plan a staged transition over a timescale to suit each individual.
- PKU trio does not contain fibre so may be better tolerated than other fibre-containing products and make transition easier.

### Practicalities

- When transitioning from a phe-free formula for infants, the unflavoured variety of PKU trio may be most useful as it is closer in flavour to a first stage medical food.
- Flavouring ideas for PKU trio are available on request from your Vitaflo representative.
- Involve children, when appropriate, in the preparation and cooking process to help them understand their diet.

## 3.2 Reducing volume further

**PKU trio** provides PE in a lower volume than phe-free formula for infants. However, there are times when an even lower volume protein substitute may be beneficial. Similarly, a ready-to-drink protein substitute can be useful for when 'out and about'. Vitaflo offers these kinds of protein substitutes and more information can be obtained from your Vitaflo representative. The meal plans below give an example of how these products can help.

	 Young children from 1 year old	 Older children
<b>Breakfast</b>	10g PE <b>PKU trio</b> Prescribed amount of natural protein Very low-protein / protein-free foods	15g PE <b>PKU trio</b> Prescribed amount of natural protein Very low-protein / protein-free foods
<b>Snack</b>		Very low-protein / protein-free snack
<b>Lunch</b>	<div style="border: 1px solid #4a7ebb; border-radius: 10px; padding: 5px; background-color: #d9e1f2;">                     10g PE from a concentrated spoonable protein substitute                       Can be given in a low volume to encourage appetite for solid foods                 </div> Prescribed amount of natural protein Very low-protein / protein-free foods	<div style="border: 1px solid #4a7ebb; border-radius: 10px; padding: 5px; background-color: #d9e1f2;">                     15g PE from a ready-to-drink protein substitute                       Can be packed in to a lunch box to take to school                 </div> Prescribed amount of natural protein Very low-protein / protein-free foods
<b>Snack</b>		Very low-protein / protein-free snack
<b>Evening meal</b>	10g PE <b>PKU trio</b> Prescribed amount of natural protein Very low-protein / protein-free foods	15g PE <b>PKU trio</b> Prescribed amount of natural protein Very low-protein / protein-free foods

It should be noted that more concentrated protein substitutes are lower in energy and fluid and so this should be considered in the daily prescription. Additional fluid should be taken with a concentrated medical food.

## 4.0 Preparation guidelines

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## 4.0 Preparation guidelines

### Dosage and Administration

To be determined by the clinician or dietitian and is dependent on age, body weight and medical condition.

### Preparation Guidelines

#### 2 LEVEL SCOOPS PROVIDE 10g PE



#### Step 1:

Measure 2 level scoops into glass/mixing cup.



#### Step 2:

Add approx 4.5 fl. oz (135 ml) of cold water.



#### Step 3:

Mix well until all of the powder is dissolved.



#### Step 4:

Drink immediately.

#### To make more than one serving:

Measure the required number of scoops and add the recommended amount of water.

Mix well until all of the powder is dissolved. A shaker can also be used to dissolve and mix the powder.

Store prepared formula in a covered container in a refrigerator and use within 24 hours. Shake or mix well before use.

### Storage

**Unopened:** PKU trio should be stored in a cool dry place.

**Once opened:** Use within one month.

### Quick preparation guide

Household measurement*	Weight of powder (g)	PE (g)	Calories (kcal)
1 scoop	16.5	5	67
1 teaspoon	3	1	12
1 tablespoon	9	2.7	37
¼ cup	36	11	146
½ cup	72	22	292

\* All household and scoop measurements are given for a level, unpacked measure taken directly from the can and are approximate. The household measurements are based on US items, so may vary to European equivalents. For accuracy, a gram scale is always recommended.

5.0

## References

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5.0

## 5.0 References

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## Appendices

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6.1 [Appendix 1 - Protein equivalent \(PE\) calculator](#)

6.2 [Appendix 2 - Preparing PKU trio to different concentrations](#)

## 6.1 Appendix 1 - Protein equivalent (PE) calculator

The table below shows the weight or scoops of **PKU trio** to achieve desired PE with corresponding energy values.

<b>PE (g)</b>	<b>Weight of PKU trio (g)</b>	<b>Scoops of PKU trio</b>	<b>Energy (kcal)</b>
5	16.5	1	67
10	33	2	134
15	49.5	3	201
20	66	4	268
25	82.5	5	335
30	99	6	402
35	115.5	7	469
40	132	8	536
45	148.5	9	603
50	165	10	670

## 6.2 Appendix 2 - Preparing PKU trio to different concentrations

The **PKU trio** calculator, found at [www.Vitaflo-VIA.com](http://www.Vitaflo-VIA.com), provides an individualised transition where concentration as well as other variables can be specified.

Concentration (kcal/ml)	Weighed amount of PKU trio (g)	Added water		Final volume		Osmolality (mOsm/kg)
		(fl.oz)	(ml)	(fl.oz)	(ml)	
0.88 (standard)	43	5 ½	167	6 ½	200	860
1.0	50	5 ½	165	6 ½	200	1040
1.2	60	5 ½	160	6 ½	200	1310
1.5	77	5	150	6 ½	200	1780

Fl.oz rounded to the nearest ½ fl.oz.



Innovation in Nutrition

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