PKU start™

A practical guide to the introduction and use of **PKU start**™, a phenylalanine-free infant formula.

Vitaflo in Association With You

Supporting education in the dietary management of rare diseases

Disclaimer

This practical guide is for the use of **PKU start** in the dietary management of an infant diagnosed with phenylketonuria (PKU). It should be utilized in conjunction with local and national protocols.

- Only to be used by healthcare professionals.
- Not for use by patients or their families/caregivers.
- For general information only and must not be used as a substitute for professional medical advice.

Important notice

PKU start is a powdered phenylalanine-free infant formula for the dietary management of phenylketonuria.

PKU start is suitable from birth.

Not for intravenous use.

For enteral use only.

Not for use as a sole source of nutrition.

PKU start must only be consumed by individuals with proven PKU under strict medical supervision.

PKU start must be used in conjunction with human milk or standard infant formula to provide phenylalanine, fluid and general nutrition requirements of the infant.

Introducing and adjusting PKU start is based on the individual needs of the infant. While practical examples are given in this guide, local practice may vary. It is the responsibility of the managing health care professional to use their clinical judgment to introduce and adjust PKU start in the most appropriate way for their individual patients.

The product information presented in this guide, although correct at the date of publication, is subject to change. To ensure accuracy, please refer to product labels.

The information contained in this guide is for general information purposes only and does not constitute medical advice. The guide is not a substitute for medical care provided by a licensed and qualified healthcare professional. This guide does not establish or specify particular standards of medical care for the treatment of any conditions referred to in this guide. Vitaflo™ International Limited and its affiliates (including Vitaflo USA, LLC) do not recommend or endorse any specific tests, procedures, opinions, clinicians, or other information that may be included or referenced in this guide.

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Symbols and abbreviations

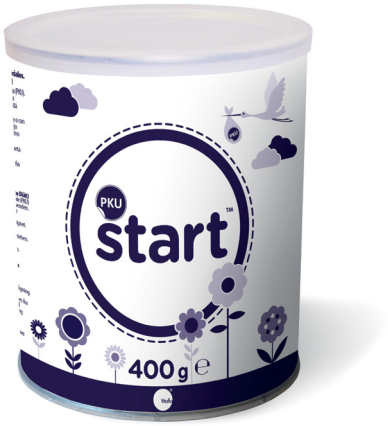
Symbol	Abbreviation	Definition
	HM **BF**	Human milk Breastfeed
	HCP	Healthcare Professional
	phe	Phenylalanine
	**phe-free formula**	Phenylalanine-free formula (**PKU start**)
	**PKU explore™**	Semi-solid spoonable medical food to support introduction of solids
	**SIF**	Standard infant formula

Contents

PKU start

PKU start is an amino acid-based powdered phenylalanine-free infant formula containing essential and non-essential amino acids, carbohydrate, fat, vitamins, minerals, arachidonic acid (ARA), and docosahexanoic acid (DHA). **PKU start** provides all the essential nutrients required by an infant, except phenylalanine. It has been developed to comply with all applicable worldwide regulations for infants with specific medical conditions such as PKU.

PKU start is for use in the dietary management of PKU from birth.



1.0 Features of PKU start

Up-to-date nutritional profile

Consistent with scientific evidence in infant formula nutrition and PKU management, including:

- DHA and ARA to help support brain and eye development[1, 2]
- Essential vitamins and minerals including calcium & vitamin D to support bone health[3].

Well tolerated

Infants with PKU demonstrate good tolerance, growth, and metabolic control in clinical evaluations[4].

2.0 Overview of feeding an infant with PKU

Newly diagnosed infants with PKU are prescribed a phe-free infant formula (**PKU start**) immediately after diagnosis is confirmed. Feeding an infant with PKU is a balance between providing phe-free infant formula alongside adequate amounts of phe from HM/SIF with the goal of keeping phe levels in target therapeutic range (120-360 umol/L)[5]. This balance can be achieved with HM or SIF as the source of phe, and a family should be supported in making the appropriate choice for their family and their infant, with relevant healthcare professionals' input as appropriate.

PKU start may be used from diagnosis in combination with HM/SIF or as a sole source of nutrition for a brief period known as a "washout" in order to achieve a rapid reduction in blood phe levels. A washout period should only be used if diagnostic blood phe levels are significantly elevated and as long as blood phe may be monitored very closely to prevent phe deficiency. Once blood phe levels approach target therapeutic range, a source of phe, either HM or SIF, is reintroduced and given in combination with **PKU start**.

Breast fed infants

Healthcare providers should support a family's decision to BF or provide HM as the intact protein source for an infant with PKU. **PKU start** combined with bottle-fed HM or feeding at the breast is able to maintain satisfactory blood phe control provided there is adequate HM available for the infant and blood phe levels can be closely monitored[6]. HM offers nutritional benefits including higher long chain polyunsaturated fatty acid concentrations and a lower phe content, 47 mg/100 ml in HM[2] compared with approximately 56 mg/100 ml in SIF[2].

Breast feeding an infant with PKU is based on the principle of giving a measured volume of **PKU start** to offset the infant's appetite for breastfeeds. Feeding a measured amount of **PKU start** alongside each breastfeed, or alternating measured feeds of **PKU start** with breastfeeds, decreases the total amount of HM consumed and therefore decreases total phe intake. Babies can still feed on demand, varying the quantity of feeds from day to day provided that the prescribed quantity of **PKU start** is given throughout the day[6]. Successful PKU management with breastfeeding is achieved via close monitoring of blood phe levels and adjustment of the prescribed volume of **PKU start** by the metabolic dietitian in order to maintain blood phe control. See sections 2.1-2.4 for more details.

SIF fed infant

There are various options for feeding an infant with SIF and **PKU start**. With the help of healthcare providers, including the metabolic dietitian, families may choose a SIF supplemented with DHA and ARA that is best for their infant and family circumstances. SIF and **PKU start** may be given in separate or mixed bottles, with a variety of feeding approaches capable of optimizing blood phe control and catering to a family's individual circumstances. See Sections 2.1-2.4 for more details.

Blood phe level monitoring

Blood phe levels are used to determine whether the volume of **PKU start** and HM/SIF should be adjusted. Expect to adjust the feeding plan weekly, especially during the first two months of life. Blood phe levels should be checked at least weekly throughout infancy[5, 6]. The quantity of phe tolerated by infants will vary and be guided by blood phe levels. Individual phe tolerance will vary significantly throughout infancy with changes in growth and development. It is vital to investigate the possible causes for changes in phe level before adjusting the feeding plan. Consider waiting for two consecutive blood phe levels to indicate the need for a feeding plan adjustment, unless the blood phe level is very low or very high.

Progression

PKU start and HM/SIF may continue to provide 100% of the infant's nutrition requirements until the age of 6 months, or when the infant is developmentally ready for the introduction of solids - see section 5.0 for more details.

Important note:
BF can continue for as long as the mother and infant wish, provided that growth and blood phe levels are satisfactory. SIF should be introduced if there is inadequate HM to provide enough phe or liquid nutrition volume for age in combination with **PKU start**. If the mother wishes to wean the infant from HM, then a gradual approach is recommended, if possible.

Principles of initiating nutrition management

If phe levels > 360 umol/L, implement use of PKU start.

Depending on diagnostic phe level and clinical circumstances, the metabolic team may consider the following strategies for initiating **PKU start**:

1. Temporarily stop HM/SIF and use **PKU start** as sole nutrition source for </= 48 hours.
2. Introduce **PKU start** in combination with HM/SIF.

Once phe levels approach the target therapeutic range, if HM/SIF has been stopped, reintroduce to tolerance.

Intact protein intake is adjusted based on individual blood phe levels. For breastfed infants, **PKU start** volumes will be adjusted with the intended effect of modifying the infant's appetite for HM.

Continue to give a combination of **PKU start** + HM/SIF to provide 100% of the infant's requirements and to achieve optimal growth and phe levels.

HM/SIF and **PKU start** should provide 100% of the infants' nutrition needs until the age of 6 months when solids are introduced or when the infant is developmentally ready for the introduction of solids.

Monitor blood phe levels weekly or more frequently as needed to achieve stability in blood phe treatment range (120-360 umol/L).

- **PKU start and phe source should be given together at each feed, or at alternating feeds to ensure nutrient availability throughout the day.**
- **If the prescribed volume of PKU start is not taken, it may cause a rise in blood phe levels.**
- **Blood phe levels are used to determine whether PKU start, SIF/HM prescription should be adjusted.**
- **The infant should be weighed at each clinic visit.**

2.1 Nutrition prescription using **PKU start** at diagnosis

The aim is to achieve a rapid reduction in blood phe levels.

If temporarily stopping intact protein and using **PKU start** alone to lower very high blood phe levels

Step 1 - Introduction of **PKU start**

- Use **PKU start** as a sole source of nutrition for 24-48 hours or until blood phe level approaches target range.
- **PKU start** should be offered on demand to the infant.

Feeding plan and considerations:

- Mix desired amount of **PKU start** per feed. A 1-2 week old infant will typically take 45-90 ml (1.5-3 fl oz) per feed.
- Encourage family to track number of wet and soiled diapers to ensure intake adequacy.
- Feeding frequency may need to be higher for babies who have not yet regained their birth weight. Family should consult with their pediatrician or metabolic dietitian.
- Encourage breastfeeding mothers to express breast milk when the baby feeds to establish and protect breast milk supply during the washout period.
- Maternal-baby skin-to-skin contact and/or a small number of short duration breastfeeds, may be continued to help promote breast milk supply and bonding during the period when breastfeeding is stopped.

Step 2 - Reintroduction of HM/SIF - **When blood levels are in the therapeutic target range.**

2.2 Example feeding plans

If a washout period is not required or reintroducing intact protein source, the following feeding plans illustrate 2 methods

A 6-day old infant diagnosed with PKU, weight 3.5 kg.

Using precise feeding volumes

PKU start & BF	PKU start & expressed HM/SIF
Estimate total volume intake per day using 150 ml/kg x 3.5 kg	
Estimated phe need = 130-430 mg/day[5]. Using 150 mg phe/day:	
Estimate amount of HM needed: **~320 ml HM** (47 mg phe/100 ml) HM will not actually be measured but this estimate gives a place to start.	Estimate amount of HM/SIF needed: **~320 ml HM** (47 mg phe/100 ml) **~250 ml SIF** (60 mg phe/100 ml).
Estimate amount of **PKU start** needed to meet remaining fluid needs.	
525 ml total volume – **320 ml HM** = **205 ml PKU start** per day.	525 ml total volume – **320 ml HM** = **205 ml PKU start** per day 525 ml total volume – 250 ml SIF = **275 ml PKU start** per day.
Divide total amount of estimated **PKU start** needed by number of feeds per day. **205 ml PKU start** / 8 feeds per day = **25 ml PKU start** per feed • Feed **25 ml PKU start** prior to each breastfeed and then allow baby to feed at breast to appetite. **OR** • Alternate feeds of **50 ml PKU start** with BF.	Establish mixing prescription per bottle by dividing HF/SIF and **PKU start** needed per bottle* • If using HM: **320 ml HM** + **205 ml PKU start** per day / 8 feeds per day = **40 ml HM** + **25 ml PKU start** per feed • If using SIF: **250 ml SIF** + **275 ml PKU start** / 8 feeds per day = **30 ml SIF** + **35 ml PKU start** per feed.

As a starting point, try to simplify the above plans into more easily measurable quantities such as:

30 ml (1 fl oz) PKU start prior to each BF. **OR** Alternate **60 ml (2 fl oz) PKU start** with BF.	**30 ml (1 fl oz) SIF** OR **45 ml (1.5 fl oz) HM** + **30 ml (1 fl oz) PKU start** per feed.

for calculating the feeding plan whether breast feeding or bottle feeding with expressed HM or SIF.

Using feeding volume percentages

PKU start & BF

= **525 ml/day** (or use baby's usual total volume intake if known).

Establish appropriate percentage of intake needed from **PKU start** and intact protein source. Consider starting with a 50/50% prescription until individual phe tolerance is better understood.

525 ml per day x 50% = **260 ml/day PKU start** + **260 ml/day HM**

(HM is not actually measured, but this is just a place to start)

Divide estimated **PKU start** volume among number of feeds per day.

260 ml PKU start / 8 feeds per day
= ~30 ml PKU start per feed

Feed **30 ml (1 fl oz) PKU start** prior to each BF and then allow baby to feed at breast to appetite.

OR

Alternate feeds of **60 ml (2 fl oz) PKU start** with breastfeeds.

PKU start & expressed HM/SIF

525 ml per day x 50% = **260 ml/day PKU start** + **260 ml/day HM** OR **SIF**

Establish mixing prescription per bottle by dividing HM/SIF and **PKU start** needed per bottle

35 ml SIF/HM + **35 ml PKU start** to make a 70 ml bottle*

Consider simplifying the above into more easily measurable quantities such as:

30 ml (1 fl oz) SIF/HM + **30 ml (1 fl oz) PKU start** per feed*

* Babies should be fed to appetite when hungry and total liquid volume per day should not be limited to establish phe level control. If the estimated volume intake does not satisfy the baby, then additional feeds either of mixed **PKU start** + HM/SIF or **PKU start** alone should be given depending on what is clinically appropriate.

2.3 Check list for blood phe monitoring

Many factors can affect blood phe levels. Always check for causes of high

Considerations for high blood phe levels:

Possible cause	Action
Excess intake of intact protein (HM/SIF)	• Confirm feeding preparation and provision is consistent with prescription • Review mixing and measuring of feeds/ formula • Adjust prescription of HM/SIF and **PKU start** to meet baby's phe tolerance
Inadequate intake of PKU start	• Ensure that adequate **PKU start** supply is available • Address symptoms that may affect tolerance such as colic, constipation, or reflux by seeking appropriate medical advice • Determine presence of short-term symptoms affecting intake such as illness, pain, teething, or vaccination • Monitor weight and increase **PKU start** prescription as needed
Catabolism or slow weight gain	• Monitor weights frequently to better understand growth trajectory • Rule out illness or infection and encourage appropriate medical treatment • Encourage optimal total volume intake and adjust feeding intervals and frequency as needed to achieve goals • Cross-check phe and calorie intake to ensure infant is meeting requirements
Change in blood monitoring routine	Encourage consistent timing of blood phe level within family's and infant's specific circumstances

or low blood phe level before making a change to the nutrition prescription.

Considerations for low blood phe levels:

Possible cause	Action
Inadequate intake of intact protein (HM/SIF) or Excessive intake of PKU start	• Confirm feeding preparation and provision is consistent with prescription • Review mixing and measuring of feeds/ formula • Ensure adequate HM available if applicable, supplement SIF as needed • Adjust prescription of HM/SIF and **PKU start** to meet baby's phe tolerance
Anabolism or rapid growth phase	• Monitor weight frequently to better understand growth trajectory • Increase phe source if blood phe level is very low; consider continuing prescription and repeating level if blood phe level is in an acceptable low range
Change in blood monitoring routine	Encourage consistent timing of blood phe level within family's and infant's specific circumstances

Monitoring Tips

For all infants, frequent monitoring of phe levels is key, but try not to make changes to a feeding plan too frequently.

Consider:

- Many factors affect phe levels; review all causes in this section
- Monitor phe level trends
- Unless phe level is very low or very high consider:
  - Continuation of the current plan
  - Monitoring 2 consecutive phe levels before adjusting prescription
- In general, do not make more than 1 change to the plan in 1 week

For phe levels that ARE very low or very high:

- Consider repeating blood phe level sooner than 1 week to guide interventions.

Remember:

Nutrition prescription adjustments made during illness or infection will be temporary and should be closely monitored

2.4 Fine-tuning the nutrition prescription

For a BF infant + PKU start

Action	If blood phe HIGH after 2 consecutive samples or after a single, very high level	If blood phe LOW after 2 consecutive samples, or after a single, very low level
	• Increase **PKU start** prior to each feed • Consider a 20-50% increase* in **PKU start** depending on severity of elevation.	• Decrease **PKU start** prior to each feed • Consider a 20-30% decrease in **PKU start** depending on severity of low.
	EXAMPLE Infant weight 5 kg	
Current feeding regimen	**30 ml (1 fl oz) PKU start** prior to every breastfeed ~8 breastfeeds per day Estimated **PKU start** per day = **240 ml (8 fl oz)**.	
Adjustment	**45 ml (1.5 fl oz) PKU start** prior to every breastfeed **OR** Give 1 full bottle feed per day of **PKU start** only, and continue with **30 ml (1 fl oz) PKU start** prior to remaining breastfeeds (~7 per day) Estimated **PKU start** per day = 300-360 ml (10-12 fl oz).	**20 ml (0.67 fl oz) PKU start** prior to every breastfeed **OR** Give 1 full breastfeed per day without **PKU start** and continue **30 ml (1 fl oz) PKU start** prior to remaining breastfeeds (~7 per day) Estimated **PKU start** per day = 160-210 ml (5-7 fl oz).

* Although a 50% increase seems high, it often coincides with a simultaneous increase in total infant feeding volume per day.

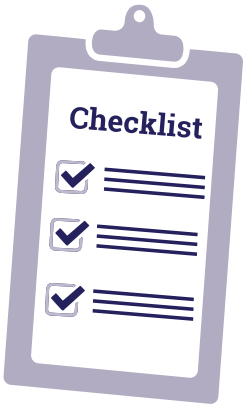
For a Bottle-fed infant + PKU start

Action	If blood phe HIGH after 2 consecutive samples or after a single, very high level	If blood phe LOW after 2 consecutive samples, or after a single, very low level
	• Increase **PKU start** per bottle • Consider a 20-50% increase* in **PKU start** depending on severity of elevation.	• Decrease **PKU start** per bottle • Consider a ~20% decrease in **PKU start** depending on severity of low.
	EXAMPLE Infant weight 5 kg	
Current feeding regimen	90 ml (3 fl oz) per feed x 8 feeds per day Bottles mixed as **30 ml (1 fl oz) PKU start** + **60 ml (2 fl oz) SIF** Estimated **PKU start** per day = **240 ml (8 fl oz)**.	
Adjustment	**45 ml (1.5 fl oz) PKU start** + **45 ml (1.5 fl oz) SIF** Estimated **PKU start** per day = **360 ml (12 fl oz)**.	**25 ml PKU start** + **65 ml SIF** (note: this is a difficult volume for families to measure, consider alternative option) **OR** Give 1 full bottle per day of SIF and continue remaining bottles (~7 per day) mixed as **30 ml (1 fl oz) PKU start** + **60 ml (2 fl oz) SIF** Estimated **PKU start** per day = **200-210 ml (~7 fl oz)**.

- If the infant is still hungry after the feed, there are different approaches that may be used to achieve satiety for the infant while maintaining blood phe control (babies should always be fed to appetite, and total feeding volume should not be restricted to achieve phe level control):
  1) Offer additional **PKU start** to achieve satiety.
  2) Offer additional mixed bottle of SIF/HM + **PKU start** to achieve satiety.

3.0 Practical feeding strategies to use with caregivers

- Be prepared with feeding supplies. It is important for HCPs to know what supplies the family/caregivers have on-hand and to ensure they can get proper supplies when needed. These include:
  - Feeding bottles with necessary measuring demarcation for baby's recipe (if mixing a large volume formula, a large volume demarcated measuring/mixing container will be needed in addition to feeding bottles)
  - Appropriately staged nipples for infant feeding
  - Adequate supply of **PKU start**
  - Adequate supply of SIF (if using)
  - HM pump and supplies if needed to express



- Review (and review again!) formula mixing instructions
  - Use **PKU start** scoop (or gram scale) to mix **PKU start**.
    Do not use scoops from other formula containers to mix **PKU start**
  - Ensure family has access to a safe water source for formula mixing
  - Inquire about the most effective written method for family to receive new recipes and mixing instructions. Review mixing at every visit
- Confirm family/caregivers are able to procure more **PKU start** and SIF (if using) when supplies are low. Consider providing written guidance on where families can obtain these formulas. Direct families to appropriate agencies and services if needed to obtain SIF at low-cost or for free.

Mixing Notes

Caregivers may choose to mix one bottle for a single feeding or a 24-hour batch at one time.

1. If preparing one bottle at a time:

- Pour the recommended amount of water into the bottle first and then add the prescribed number of scoops or grams of **PKU start** powder
- Cap the bottle and shake well
- Feed the baby immediately
- Once feeding begins, use contents within 1 hour or discard

2. If preparing a 24-hr batch:

- Pour the recommended amount of water into the container first and then add the prescribed number of scoops or grams of **PKU start** powder. When mixing large volumes, consider using a gram scale instead of scoops for improved accuracy
- Cap the container and shake well
- Refrigerate freshly prepared formula and use contents within 24 hours. Re-shake before use. Refrigerator temperatures should be maintained at 35-40°F (2-4°C).

3.1 Practical points for effective communication between HCPs and Caregivers

- **Establish lines of communication between HCP and caregiver/family -** phone calls, e-mail, text and/or the medical record portal may all be used. Ensure caregivers/families are comfortable using communication method.
- **Keep information simple and practical and check family/caregiver understanding of information.**
  - Allow time for questions and encourage questions between visits.
  - Consider written feeding plans.
- **Encourage questions!** Caregivers should be encouraged to ask questions and speak up whenever they do not understand. Effective and open lines of communication as well as appropriate teaching methods are critical for caregiver success.
- **Educate all caregivers.** Let primary caregiver(s) know that anyone taking care of the baby is welcome at clinic visits and education pieces may be provided for all caregivers depending on their needs.
- **Establish frequency of phe levels and clinic visits.** Ensure caregivers understand what communication method will be used to report results and adjust the diet between visit.
- **Inform other HCPs, including the primary care physician, of the management plan.**
- **Direct caregivers to appropriate patient/family support groups and appropriate information platforms.**
- **Remember that different patients/families succeed with different communication methods;** be as adaptable as you can within your clinic's capabilities.

4.0 Directions for preparation, use, and storage of PKU start

Preparation Guidelines

Wash hands well.

Sterilize feeding equipment according to manufacturer's instructions.

Boil fresh water and leave to cool for no more than 30 minutes to ensure it remains at a temperature of at least 158°F/70°C. Do not use artificially softened water or repeatedly boiled water.

Measure out the required amount of water into the bottle.

Using the scoop provided, add the prescribed number of scoops of **PKU start** to the water, leveling each scoop off with the back of a clean dry knife. Do not press the powder into the scoop.

Place the sterilized nipple and cap on the bottle and shake well until all the powder has dissolved.

Cool to drinking temperature (approx. 99°F/37°C.) Always test the temperature before feeding by shaking a few drops onto the inside of your wrist – the formula should feel warm but not hot.

It is important for caregivers to carefully follow the instructions for the preparation, use and storage of **PKU start**. The standard dilution of 21 kcal/fl oz or 0.69 kcal/ml is made by adding 1 level scoop of **PKU start** (4.7 g) to 30 ml (1 fl oz) of water. Use only the scoop provided in the can or a gram scale for greatest accuracy.

Do not reheat **PKU start** once feeding has started.

Do not heat **PKU start** in a microwave as uneven heating may occur and could cause a burn.

Do not boil **PKU start**.

Infants should be supervized at all times when feeding.

Water (fl oz/ml)		PKU start powder (scoop)	PKU start powder (g)	Approximate Final Volume (fl oz/ml)	
1	30	1	4.7	1.1	33
2	60	2	9	2.2	67
4	120	4	19	4.4	133
6	180	6	28	6.7	200
8	240	8	38	8.9	266

Storage

Unopened: PKU start should be stored in a cool, dry place.

Once opened: Use within 3 weeks. Always replace container lid after use.

Use by Best Before date.

5.0 Introduction of solids and the role of PKU explore

The overall goal of the introduction of solid foods is to progressively transition from an exclusively liquid diet to a varied diet, to meet both the nutritional and developmental needs of growing infants. During this transition, the metabolic dietitian and PKU parents/caregivers will work toward:

- Maintaining satisfactory growth and metabolic control.
- Encouraging oral motor and self-feeding skills within the limits of the PKU diet.
- Meeting a growing need for protein between 6–12 months of life without increasing liquid volume and within the limits of the PKU diet.

In a non-PKU infant, the growing protein need would be met with introduction of protein containing solids; however, incorporating higher protein solids is not a safe option for infants with PKU. The most common approach to meet growing total protein needs without exceeding phe tolerance is to increase the volume of liquid phe-free infant formula. This may prolong reliance on bottle feeding, impact appetite for food, and delay the natural progression to a varied solid diet. Decreased reliance on bottles, the introduction of liquids from a cup, and spoon- and/or self-fed solids enhances oral motor feeding skills and broadens the child's range of tastes and textures over time.

PKU explore supports the transition from an exclusively liquid diet to a varied diet incorporating solid foods with less reliance on excessive volumes of PKU infant formula beyond the typical amount at this stage of development.

HM/SIF + **PKU start**

3 chopped/textured meals per day consisting of the tolerated allowance of intact protein and very low protein foods to appetite + **PKU explore** **PKU start** **Sippy cup**

For more detail refer to the VIA website **vitaflousa.com/via** - A practical guide for the introduction of solid foods and **PKU explore™** in the PKU diet.

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