

Healthcare Professional Guide

Use of K·Vita in the dietary management of children with drug resistant epilepsy





Contents

| | | Page |
|---|--|------|
| 1 | Overview of K·Vita | 2 |
| 2 | Key points about the use of K·Vita | 2 |
| 3 | Recommended daily amount for children | 3 |
| 4 | Advising on the use of K·Vita | 4 |
| | 4.1 Introduction of K·Vita | 4 |
| | 4.2 The 'Guide for children taking K·Vita ' | 5 |
| | 4.3 Measuring K·Vita | 6 |
| | 4.4 Taking K·Vita | 6 |
| | 4.5 Four-week plans for the introduction of K·Vita | 7 |
| | 4.6 Continuing with K·Vita | 7 |
| | 4.7 Changing from taking K·Vita four times daily to three | 7 |
| 5 | Side effects from K·Vita | 8 |
| | 5.1 What to look out for | 8 |
| | 5.2 Managing side effects if they occur | 8 |
| 6 | Diet whilst taking K·Vita | 9 |
| | 6.1 Why avoid sugar? | S |
| | 6.2 Foods and beverages high in sugar | S |
| | 6.3 Sources of information on sugar intake | S |
| 7 | How to store K·Vita | 11 |
| 8 | Recommended support provision and follow-up | 11 |
| 9 | Summary - Advising on the use of K·Vita in 7 steps | 12 |

For further information on the use of **K·Vita** for the dietary management of epilepsy in children, please contact Vitaflo using the details on the last page of this guide or at **www.K-Vita.co.uk**

Resources for the use of **K·Vita** can be accessed on the Vitaflo VIA website **www.vitaflo-via.com/**

IMPORTANT

This guide is intended for use only by healthcare professionals advising on the use of K·Vita by children with drug resistant epilepsy

Overview of K·Vita

K·Vita is:

- Food for Special Medical Purposes for the dietary management of drug resistant epilepsy in adults and in children from 3 years of age
- A strawberry flavour, thickened liquid. With sweetener
- A specific blend of fats medium chain triglycerides (MCT). K.Vita contains capric/decanoic acid (C10) and caprylic/octanoic acid (C8) in the ratio C10:C8, 80:20
- Not suitable for use as a sole source of nutrition
- Suitable for oral use or may be given via an enteral feeding tube
- Consumed 'as is', or after mixing into suitable foods and beverages, for example, unsweetened yogurt or plain milk





Key Points about the use of K·Vita

- IMPORTANT: To establish gastrointestinal (GI) tolerance to MCT, K·Vita must be introduced slowly, in measured amounts, over four weeks
- During this time, **K·Vita** is taken four times each day with meals and an evening or bedtime snack
- Once established on **K·Vita**, it can be taken three times daily instead of four
- K·Vita should be consumed regularly throughout the day, always with food (preferably at mealtimes), before, during or after eating
- **K·Vita** is consumed as part of a child's usual diet but foods and beverages high in sugar should be avoided



Recommended Daily Amount for Children

One pack (1 x 120ml) of K·Vita.

1. Plans for the introduction of up to one pack per day of **K·Vita** over four weeks are available in the 'Guide for children taking **K·Vita**'. More information is in Section 4 (page 4) of this guide.

The daily amount tolerated and/or required may be lower or higher than one pack per day. This should be determined on an individual patient basis.

It may be dependent on factors such as symptoms of epilepsy, body size, daily energy requirement and GI tolerance of MCT.

Total intake must not exceed two packs (2 x 120ml) per day.

- **2.** During the introduction of **K·Vita** for the dietary management of drug resistant epilepsy, if an improvement is noticed from using a lower amount than the recommended daily intake, it is not necessary to make any further increases in the amount taken. Not every child needs to take one pack of **K·Vita** per day.
- **3.** At the end of the four-week introduction, if one pack of **K·Vita** per day for the dietary management of drug resistant epilepsy is tolerated but there is no noticeable improvement:
 - Continue with this amount to establish if this will happen over time.
 and/or
 - Make further, slow, measured increase to the amount of **K·Vita** taken, **up to a maximum of two packs per day.** This must be done on an individual patient basis to determine how much **K·Vita** is required.
- **4. K·Vita** can also be prescribed for a child as a percentage of their daily energy requirements. A dietary assessment, undertaken by a paediatric dietitian, will be required to establish the amount of **K·Vita** to aim for during the introduction. A maximum of 35% of daily energy requirements can be provided by **K·Vita** using this approach, but total intake should not exceed two packs (240ml) per day.

A personalised introduction plan must be given to parents or caregivers to follow. Resources for creating individualised introduction plans are available at:

www.vitaflo-via.com/

5. Monitoring and follow-up of patients during, and at the end of the introduction of **K·Vita**, and long-term is advised ensure efficacy (Section 7, page 11).



Advising on the use K·Vita

4.1 Introduction of K·Vita

IMPORTANT

- MCT is associated with symptoms of GI intolerance, including abdominal pain, bloating and diarrhoea. This is related to how it is digested and absorbed by the body¹
- However, the body can adapt to MCT over time, provided that small quantities are taken at first, the amount is built up gradually and carefully, and it is always consumed with food^{2, 3}
- As K·Vita is a blend of MCT, a slow, incremental introduction of measured quantities over four weeks, up to the recommended daily amount, is crucial. This approach can help minimise side effects associated with GI tolerance of MCT
- It may seem that it will take a long time to introduce **K·Vita**. However, starting with small quantities and building up the amounts gradually by following the four-week plan is definitely worthwhile. Children can be very sensitive to **K·Vita**, especially at first. Most need time to accept it and to get used to taking it on a daily basis



4.2 The 'Guide for children taking K·Vita'

This provides information and advice on:

- $\mathbf{K} \cdot \mathbf{Vita}$ and what it is for
- Measuring and taking K·Vita
- Following the introduction plan
- Possible side effects from **K·Vita** and how to manage these
- Continuing to eat their usual diet
- Identifying foods and beverages high in sugar, why they should be avoided, and alternatives to have instead
- Storing K·Vita
- Getting prescriptions of K·Vita
- Four-week plans for introducing **K·Vita**



To help with the acceptance of **K·Vita**, establish GI tolerance and promote adherence with taking it daily, it is important to explain and discuss all the information in the guide with parents or caregivers.

Ensure a named person and contact details are provided for them to access to support with giving **K·Vita** to their child.

Printed copies of the guide are available from Vitaflo for you to supply to parents and caregivers. The guide can also be viewed on-line and downloaded from **www.vitaflo-via.com/**

4.3 Measuring K·Vita

K·Vita needs to be measured accurately by using:

A measuring cup marked with 5ml graduations

OR

Household tea and tablespoons

OR

Measuring spoons (5ml and 15ml)

If possible, please provide measuring cups with 5ml graduations from the hospital, clinic or pharmacy. Alternatively, advise that measuring cups marked with 5ml graduations and sets of measuring spoons can be purchased from on-line stores or shops that sell kitchenware.



4.4 Taking K·Vita

K·Vita should be shaken well before use.

It can be served at room temperature or chilled straight from the fridge.

K·Vita can be drunk or eaten (using a small spoon) directly from the measuring cup.

If a spoon is used for measuring, $\textbf{K}\boldsymbol{\cdot}\textbf{Vita}$ can be taken directly from this.

Alternatively, after measuring, K·Vita can be:

- Transferred into another vessel and consumed from this
- Mixed into unsweetened yogurt or plain milk.

 The whole portion must be drunk or eaten so all the **K·Vita** is taken

Any **K·Vita** adhering to the sides of the measuring cup or other vessel should be scraped off using a small spoon and consumed.

4.5 Four-week plans for the introduction of one pack (120ml)* K·Vita per day

Charts are included in the 'Guide for children taking **K·Vita**' and can also be downloaded and printed out as separate pages from **www.vitaflo-via.com/**

- Patients and/or caregivers can choose to measure out K.Vita using a measuring cup or household or measuring spoons. Introduction plans are available for each method. Each starts with a daily amount of 15ml, divided into three portions of 5ml. This increases to 20ml daily (four portions of 5ml) after two days
- Gradual, incremental increases of 5ml per day (or every other day) are made over four weeks, up to the recommended daily amount for children of one pack (1 x 120ml) of **K·Vita** per day (four portions of 30ml)
- If desired, the pages in the plans can be printed out (or torn out of the paper copy) to put up somewhere visible, for example, on a notice board or on the fridge door
- Whenever K.Vita is taken, this should be recorded on the chart to record progression through the introduction
- * Blank charts can be downloaded from **www.vitaflo-via.com** and used to create personalised introduction plans. An introduction calculator is also available for this purpose.

4.6 Continuing with K·Vita

Children should be reviewed during and/or at the end of the four-week introduction of **K·Vita** to find out how they are getting on with the product, how much they are taking every day and if it is helpful for their epilepsy.

If it is decided they are to carry on with $K \cdot V$ ito they can continue to be given the daily amount that is right for them, in measured amounts, at regular times throughout the day, and always with food.

Once established on **K·Vita** progress should be monitored at routine clinic appointments. See also Section 7: 'Recommended support provision and follow-up' (page 11).

4.7 Changing from taking K·Vita four times daily to three

Once **K·Vita** has been introduced and the child is established on the amount that is right for them, it can be taken three times daily instead of four, if preferred. Instructions for changing from four portions of 30ml daily to three of 40ml daily are provided in the 'Guide for children taking **K·Vita**'.

If the amount of $\mathbf{K} \cdot \mathbf{Vita}$ taken is lower or higher than 120ml (one pack) daily, the $\mathbf{K} \cdot \mathbf{Vita}$ calculator can be used for making individualised plans to change from four to three times daily: $\mathbf{www.vitaflo-via.com/}$

The advice in the 'Guide for children taking **K·Vita**' is for the healthcare professional to be contacted before making this change. If side effects occur that do not resolve (page 8), **K·Vita** may be best taken four times daily again.

Side-effects from K·Vita

5.1 What to look out for

Consumption of MCT can cause symptoms of GI intolerance¹. Not every child who takes **K·Vita** will be affected, as building up the amount gradually and always having it with food can help to minimise side-effects^{2, 3}. However, some may experience one or more of the following during the introduction period, and/or once established on it:

- Vomiting
- Nausea
- Abdominal pain/discomfort
- Bloating
- Feeling full
- Excessive burping
- Excessive flatulence (wind)
- Diarrhoea
- Constipation



5.2 Managing side effects if they occur

Side effects are usually mild and disappear over time and persistence with taking **K·Vita**. Check that **K·Vita** is always being taken with food and that the plan to introduce it slowly, in measured amounts, is being followed. If side effects are occurring despite this, the advice in the 'Guide for children taking **K·Vita**' (Section 3) is to try one or more of the following:

- If in week one of the introduction plan, take a one or two-day break, then restart from the beginning
- Reduce the amount of **K·Vita** taken. Go back a day or two in the introduction plan (or to when side effects were first noticed). Stay on that amount until things improve. Then, start increasing again, according to the plan
- Make increases of **K·Vita** more slowly, for example, every two or three days instead of every day

GI tolerance to MCT can take time to be established, so encouragement to continue with **K·Vita** may be needed before considering stopping it. An individualised plan may be helpful, for example, to extend the duration of the introduction from four to six weeks. For further information, go to **www.vitaflo-via.com/**

The 'Guide for children taking **K·Vita**' advises parents or caregivers to contact their child's healthcare professional if side-effects continue after trying these suggestions, and if any other symptoms occur which they think may be caused by **K·Vita**.

6

Diet Whilst Taking K·Vita

K·Vita is consumed by children as part of their usual diet but they should avoid foods and beverages high in sugar.

6.1 Why avoid sugar?

K·Vita will provide children with a proportion of their daily energy intake. Consequently, in comparison to the amount of food they ate before starting **K·Vita**, they may want to eat less. As advised during the clinical trial of **K·Vita**³, to help minimise the impact of any reduction in food intake and optimise the nutritional quality of the diet, the avoidance of foods and beverages high in sugar is recommended. Conversely, if no compensatory reduction occurs when taking **K·Vita**, avoidance of foods and beverages high in sugar may help prevent excess energy intake.



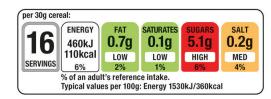
6.2 Foods and beverages high in sugar

The 'Guide for children taking **K·Vita**' explains that foods and beverages high in sugar, such as sweets, biscuits and fizzy drinks are generally low in nutrients and high in calories (energy). Reducing intakes of these items (especially if consumed regularly, for example, every day) whilst taking **K·Vita** can help ensure the diet is as nutritious as possible.

Information is provided to aid identification of foods and beverages high in sugar:

For packaged foods and drinks, looking out for the 'front of pack nutritional label' is advised.

If the product has a high sugar content per serving, the sugars section will be red



Note: K·Vita does not contain sugar. The sweet taste is from sweetener (sucralose)

The table below is included in the child patient guide to give examples of high sugar products and lower sugar alternatives:

| High in sugar | Offer these instead | | |
|--|--|--|--|
| Fizzy drinks, juice drinks, energy drinks | Water. Diet, sugar-free or no-added sugar drinks | | |
| Flavoured and sweetened milk drinks (for example, milkshakes, hot chocolate) | Milk - plain, or flavoured with sugar-free milk flavourings | | |
| Buns, cakes, pastries, biscuits Sweets and chocolate | Malt loaf, fruited teacake, scone, scotch pancakes, oat cakes, crackers, plain rice cakes, bread or toast, bagel, bread roll - spread with butter, margarine, cheese, hummus, nut butter Chopped vegetables with hummus Plain popcorn Fresh or tinned fruit (in juice, not syrup) | | |
| Ice cream 'Corner' (split pot) yogurt Puddings | Plain yogurt or fromage frais - add fresh or tinned fruit (in juice, not syrup) Sugar-free jelly | | |
| Breakfast cereals such as frosted flakes, honey crunch cereal, chocolate cereal | Porridge Wheat or oat breakfast biscuits 'no added sugar' muesli Shredded wholegrain | | |

- Some foods that naturally contain sugar plain milk, yogurt and fromage frais, and fruits and vegetables are good sources of nutrients such as vitamins, minerals, protein, and fibre and can be given to children. However, fruit juices, vegetable juices and smoothies are sugary, and the advice is to limit these to a maximum of 150ml per day (see section 6.3)
- It may be easier for parents and caregivers to make a few smaller changes at first, for example:
 - Not adding extra sugar (or honey or syrup) to foods and beverages such as breakfast cereal or hot milky drinks
 - Changing sweetened fizzy drinks or squashes/cordials to the sugar-free or diet varieties
 - Diluting pure fruit juices at least $\frac{1}{2}$ and $\frac{1}{2}$ with water (for example, 100ml juice plus 100ml water)
 - Giving smaller portions of sweet foods such as chocolate or cake, then swapping over to lower sugar alternatives

6.3 Sources of information on sugar intake

The information provided by these websites may be helpful to you if parents or caregivers have questions about their child's diet and sugar intake:

The Eatwell Guide:

www.nhs.uk/live-well/eat-well/how-to-cut-down-on-sugar-in-your-diet/

- NHS Healthier Families: www.nhs.uk/healthier-families/food-facts/sugar/
- The British Dietetic Association has guidance on appropriate daily intakes of sugar based on age: www.bda.uk.com/resource/sugar.html

If there are concerns that a child is malnourished or obese, either before starting or once established on **K·Vita**, then referral to a paediatric dietitian for dietary assessment and advice should be made. A daily micronutrient supplement to ensure dietary needs are adequate may also be indicated.



How to store K.Vita

Unopened: Store in a cool, dry place.

Once opened: Recap unused portion, refrigerate and use within 48 hours or within 6 hours at room temperature.

8

Recommended Support Provision and Follow-up

- 1. Go through the 'Guide for children taking **K·Vita**' with parents or caregivers
- 2. Provide contact details for access to help with **K·Vita**-related issues
- 3. Arrange a prescription for **K·Vita** via the child's GP or the **'Vitaflo to You'** home delivery service: **www.nestlehealthscience.co.uk/vitaflo/vitaflo-to-you**
- 4. Monitor adherence and efficacy:
 - During and/or at the end of the 4 week introduction of **K·Vita**
 - At three months
 - On an ongoing-basis: as part of routine clinical care.
- 5. Refer any concerns with dietary intake and/or nutritional status to a paediatric dietitian

9 Summary

Advising on the use of K·Vita in 7 steps:

- Give copies of the 'Guide for children taking **K·Vito**' and some measuring cups (or advise on purchasing these or measuring spoons)
- Explain that **K·Vita** is consumed as part of their child's usual diet but to avoid foods and beverages high in sugar
- IMPORTANT: Explain the introduction plan, how to measure K·Vita with measuring cups or spoons, and how to manage any symptoms of GI intolerance
- Provide contact details for access to support with the introduction of **K·Vita** (as this is an important time) and for its continuing use
- Arrange for a prescription of K·Vita via the GP or 'Vitaflo To You' www.nestlehealthscience.co.uk/vitaflo/vitaflo-to-you
- Plan follow-up: make contact during and/or towards
 the end of the introduction of **K·Vita**. If use continues,
 review at three months after **K·Vita** is started, then as part
 of routine care
- At follow-up: establish GI tolerance of, adherence to, and efficacy of **K·Vita** and advise accordingly. Refer any concerns with dietary intake and/or nutritional status to a paediatric dietitian

References

- 1. 1. Marten B, Pfeuffer M, Schrezenmeir J. Medium-chain triglycerides. International Dairy Journal. 2006 Nov 1; 16(11): 1374-82.
- 2. Sills MA, Forsythe WI, Haidukewych D, MacDonald A, Robinson M. The medium chain triglyceride diet and intractable epilepsy. Archives of disease in childhood. 1986 Dec 1; 61(12): 1168-72.
- 3. Schoeler NE et al. K. Vita: a feasibility study of a blend of medium chain triglycerides to manage drug-resistant epilepsy Brain communications. 2021; 3(4): fcab160



Food for Special Medical Purposes.
With sweetener.
Strawberry flavour.

K·Vita is a thickened liquid containing a specific blend of medium chain triglycerides (MCT). For the dietary management of drug resistant epilepsy in adults and in children from 3 years of age.

Recommended Intake and Administration

To be determined by the clinician or dietitians as it is dependent on the age, body weight and medical condition of the patient.

Shake well before use.

Important Information

Use under medical supervision.

Suitable from 3 years of age.

Not suitable for use as a sole source of nutrition.

Not suitable for use during pregnancy and lactation.

Not suitable for individuals unable to metabolise MCT, for example, those with medium chain acyl-CoA dehydrogenase deficiency (MCADD).

For enteral use only.

Use as directed by the clinician or dietitian

Introduce **K·Vita** slowly and in measured amounts.

Always take with food.

Take regularly throughout the day, preferably at mealtimes.

Consume as part of your usual diet but avoid foods and beverages high in sugar.

Suitable for tube feeding.

For further product information please contact your local Vitaflo representative, call our **Nutrition Service Helpline +44 (0)151 702 4937** or visit our website **www.vitafloweb.com**



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