



Healthcare Professional Guide

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



Enhancing Lives Together



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This practical guide is intended for use only by healthcare professionals advising on the use of **K·Vita** in adults and children with drug resistant epilepsy.

The advice provided in this guide is based on the experience gained from the **K·Vita** clinical trial¹ and real world evidence collected as part of the **K·Vita** service evaluation up until the date of publication (see back cover).

For further information about the use of **K·Vita** for the dietary management of epilepsy in adults and children, please contact Vitaflo (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® in Association with You (VIA) website **www.vitaflo-via.com/kvita**

IMPORTANT INFORMATION - K·Vita

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 who cannot metabolise the medium chain fatty acids (C8 and/or C10 fatty acids), for example those with medium chain acyl-CoA dehydrogenase deficiency (MCADD), multiple acyl-CoA dehydrogenase deficiency (MADD) or carnitine cycle defects

For enteral use only

1

Overview of K·Vita

K·Vita is:

- Food for Special Medical Purposes for the dietary management of drug resistant epilepsy
- A specific blend of fats (MCT). **K·Vita** contains the medium chain fatty acids capric/ decanoic acid (C10) and caprylic/octanoic acid (C8) in the ratio C10:C8, 80:20
- A thickened liquid. With sweetener
- Consumed orally 'as is', or after mixing into suitable foods or beverages, for example, unsweetened yogurt or plain milk
- Suitable for tube feeding. Guidance is available at **www.vitaflo-via.com/kvita**

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Key points about the use of K·Vita

- 1 IMPORTANT:** To establish gastrointestinal (GI) tolerance to MCT, **K·Vita must be introduced slowly, in measured amounts, over a minimum of four weeks.** However, the speed of introduction is dependent on individual tolerance (**Section 5**).
- 2 During the introduction and once established on **K·Vita**, the daily amount should be divided up into three or four equal portions
- 3 **K·Vita** should be consumed regularly throughout the day, always with food (preferably at mealtimes), before, during or after eating
- 4 **K·Vita** is consumed as part of the adult or child's usual diet (**Section 6**)

3

Clinical safety and monitoring

The possibility of a metabolic disorder that impairs fat metabolism must be excluded before a patient starts **K·Vita**.

During the clinical trial of **K·Vita**¹, biochemical blood and urine analyses typically used to monitor patients on ketogenic diets were performed to determine and monitor clinical safety. No clinically significant changes were reported.

Real world evidence collected as part of the **K·Vita** service evaluation shows that biochemical monitoring of adults and children varies.

There is currently insufficient evidence to make specific recommendations regarding biochemical monitoring for patients on **K·Vita**. Therefore monitoring is at the discretion of the healthcare team.

4

Daily amount of K·Vita

There is no set recommended daily amount of **K·Vita** as it depends on individual tolerance and efficacy. Daily intakes for adults (**Section 4.1**) and children (**Section 4.2**) are for guidance only when planning the introduction of **K·Vita** and are based on median daily intakes by participants in the clinical trial¹.

However, the maximum amount of K·Vita advised for consumption by an adult or child is two packs (240ml) per day. Intakes exceeding this volume may not be comfortably tolerated, and due to the energy provided, compromise the nutritional quality of the diet by displacement of food (**Section 6.2**).

4.1 Adults

Two packs (240ml) of K·Vita per day



The daily amount tolerated and/or required by an adult should be determined on an individual patient basis. It may be dependent on factors such as clinical condition, body size, daily energy requirements and GI tolerance of MCT. Some adults may require less than two packs (240ml) per day for efficacy.

4.2 Children

One pack (120ml) of K·Vita per day



The daily amount tolerated and/or required by a child should be determined on an individual patient basis. It may be dependent on factors such as clinical condition, body size, daily energy requirements and GI tolerance of MCT. Some children may require less than one pack (120ml) per day for efficacy. Others may require more, provided the advised maximums for daily energy intake from **K·Vita** (35%) and/or amount (two packs, 240ml) are not exceeded.

Children only: Prescribing K·Vita as a percentage of daily energy requirements

Up to a maximum of 35% of daily energy requirements can be provided by **K·Vita**, but total intake should not exceed two packs (240ml) per day.

A dietary assessment must be undertaken by a paediatric dietitian to determine the daily energy requirements of the child. From this, a daily amount to aim for can be calculated and an individualised introduction plan created using the **K·Vita** calculator <http://vitaflo.co/k-vita-calculator>

5.1 Establishing tolerance to K·Vita

- ▶ MCT is associated with symptoms of GI intolerance, including abdominal pain, bloating and diarrhoea. This is related to how it is digested and absorbed²
- ▶ However, adaptation to MCT occurs over time, provided that small quantities are taken at first, the amount is built up gradually, and it is always consumed with food³
- ▶ As **K·Vita** is a blend of MCT a slow, incremental introduction in measured quantities up to the individual daily amount is crucial

5.2 Introduction plans

Experience of use from the Service Evaluation shows that **K·Vita** can be successfully introduced over four weeks. However, some adults and children may require longer, for example, an introduction extending over six or eight weeks. They will need an introduction plan created specifically for them (**Section 5.3**)

5.3 Creating an individual K·Vita introduction plan

The **K·Vita** Calculator is available at <http://vitaflo.co/k-vita-calculator> to create individualised introduction plans.

This tool can be used to specify the duration of the introduction (over four, five, six, seven, or eight weeks) and the frequency that **K·Vita** is taken (three or four times daily). After entering a daily amount to be reached at the end of the plan (**Section 4**), a schedule is generated that details day by day, week by week, how much **K·Vita** to measure out and when to take it. The plan can be printed out and given to the adult or child to follow.

5.4 Four-week pre-prepared introduction plans

These are available at <http://www.vitaflo-via.com/kvita>.

- ▶ One is intended for children, to introduce up to one pack (120ml) of **K·Vita** daily using measured increments of 5ml taken four times daily with food at each of three meals and at bedtime.
- ▶ The other is intended for adults, to introduce up to two packs (240ml) daily using measured increments of 10ml taken four times daily with food at each of three meals and at bedtime.

5.5 During the introduction of K·Vita

Advise the adult or child to carefully follow their introduction plan to help minimise side effects and establish GI tolerance to MCT (**Section 8**). If an adult or child has side effects whilst introducing **K·Vita**, their plan can be adjusted by using the **K·Vita** Calculator, for example, to slow the rate of increase by extending the introduction from four to six weeks, and/or reducing the daily amount the adult or child is aiming to have reached at the end of the plan (**Section 8**).

5.6 Determining individual requirements of K·Vita

The daily amount required for the dietary management of epilepsy is very individual. **Section 4** contains guidance on daily amounts to aim for during the introduction.

If a lower daily amount of **K·Vita** is reached before the end of the introduction plan, no further increase is necessary.

5.7 At the end of the K·Vita introduction plan

At this stage, a review of the amount being taken daily, and product adherence, GI tolerance, acceptability and efficacy is advised.

- ▶ The daily amount taken can be continued if it is efficacious
- ▶ If the daily amount reached is tolerated but no benefit is observed, it may be worthwhile continuing with this for an agreed period, for example, six months, to assess if any improvement occurs over time
- ▶ Alternatively, (or after waiting to see if benefit is experienced with time), further, gradual increase in the daily amount taken be made to determine the effect, up to a maximum amount of two packs (240ml) per day (adults) and/or 35% of daily energy requirements (children) (**Section 4**)
- ▶ Use the **K·Vita** Calculator to create a plan for increasing the daily amount taken
<http://vitaflo.co/k-vita-calculator>

Although it may seem that it will take a while to introduce **K·Vita**, it is time well spent. A slow, careful approach was found to be beneficial during the clinical trial¹ as it helped to minimise the side effects associated with MCT.

Adults and children can be extremely sensitive to **K·Vita**, especially at first, and most need time for GI tolerance to be established.

Practical aspects and dietary intake

6.1 Measuring and taking K·Vita

K·Vita needs to be measured accurately by using:

A measuring cup marked with 5ml or 10ml graduations

OR

Household spoons (tea (5ml), dessert (10ml), table (15ml))

OR

Measuring spoons (5ml, 10ml, 15ml, 20ml, 30ml, 60ml)



1. Shake the pack well before use.
2. **K·Vita** is best served at room temperature but this is personal preference as it can also be consumed chilled or frozen
3. **K·Vita** can be taken directly from the spoon or cup used to measure it out
4. Alternatively, after measuring out, it can be:
 - Transferred into another vessel and consumed from this
 - or
 - Mixed into a suitable food (such as yougurt, breakfast cereal or porridge), or beverage (for example, milk or a fruit smoothie)

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

Any adhering to the sides of the vessel should be scraped off using a small spoon and consumed
5. If **K·Vita** thickens, the following advice may help:
 - Boil water in a kettle and leave it to cool for 30 minutes,
 - Fill a cup or jug half full with the water, and put in the pack of **K·Vita** for 10 minutes.
 - Measure out and use as above.

6.2 Dietary intake whilst taking K·Vita

K·Vita can be consumed as part of the adult or child's usual diet. This will be a regular, normal diet, or for some, a special diet for the dietary management of a medical condition (**Section 6.3**).

K·Vita will provide a proportion of daily energy intake. Consequently, in comparison to the amount of food habitually consumed beforehand, some adults and children may eat less overall. During the **K·Vita** clinical trial¹, guidance was given on reducing foods and beverages high in sugar (especially if consumed regularly), to help optimise the nutritional quality of the diet. This advice may be appropriate for some adults and children taking **K·Vita** as it may minimise the impact of any natural reduction in food intake.

Conversely, if no compensatory reduction in food consumption occurs, avoidance of foods and beverages high in sugar may help prevent excess energy intake and inappropriate weight gain.

These websites may be helpful if patients or caregivers have questions about their diet:

📌 The Eatwell Guide: <https://www.nhs.uk/live-well/eat-well/food-guidelines-and-food-labels/the-eatwell-guide/>

📌 NHS Healthier Families: www.nhs.uk/healthier-families/food-facts/sugar/

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

If there are concerns that an adult or child is malnourished or obese, either before starting or once established on **K·Vita**, then referral to a dietitian for dietary assessment and input should be made. Whilst taking **K·Vita**, a daily micronutrient supplement may be indicated to ensure dietary needs are adequately met.

6.3 Use of **K·Vita** in special diets, including ketogenic diets

K·Vita can be taken as part of a special diet for a medical condition in whom its discontinuation is inappropriate, for example, an exclusion diet for a food allergy.

Real world evidence from the service evaluation shows that **K·Vita** is being included as part of ketogenic diets. For example, it is being taken by patients with drug-resistant epilepsy in whom the ketogenic diet was efficacious whilst transitioning back to a normal diet (with or without **K·Vita**), and by those with Glut-1 deficiency syndrome.

Examples of use as part of the ketogenic diet are:

- 📌 In exchange for the usual source of MCT (oil, emulsion and/or powder)
- 📌 To replace a proportion of the long-chain triglyceride content of meals, snacks and/or enteral feeds

Note: The daily meal plan of the adult or child on the ketogenic diet may need to be adjusted to accommodate the energy and fat intake from **K·Vita**.



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The 'Guide for adults and children taking K·Vita'

The guide contains information and advice for patients and caregivers on:

- ▮ **K·Vita** and what it is for
- ▮ Measuring **K·Vita**
- ▮ Taking **K·Vita**
- ▮ Following the introduction plan
- ▮ General information on diet (with links to websites) and advice on reducing sugar intake, if required
- ▮ Possible side effects and how to manage these
- ▮ Storage

Printed copies of the guide, pre-prepared four-week introduction plans for introducing one or two packs of **K·Vita** and blank charts for creating individualised introduction plans are available from your Vitaflo representative.

They can also be viewed on-line and downloaded from www.vitaflo-via.com/kvita

To help establish GI tolerance and promote adherence with taking K·Vita every day, it is recommended to:

1. Explain and discuss the information contained in the guide with the adult or child, as appropriate, and their parents or caregivers
2. Go through their individual introduction plan or the pre-prepared version with them, and provide a copy they can follow
3. Provide appropriate dietary advice
4. Provide contact details to enable them to access continued advice and support whilst introducing and taking **K·Vita**














Side-effects from K·Vita

8.1 What to look out for




Consumption of MCT can cause symptoms of GI intolerance². However, not everyone who takes **K·Vita** will be affected. Building up the amount gradually and always taking it with food can help to minimise side-effects^{1,3}.

Some adults and children may experience one or more of the following whilst introducing **K·Vita**, which is the most likely time for them to occur:

-  Vomiting
-  Nausea
-  Abdominal pain/discomfort
-  Bloating
-  Feeling full
-  Excessive burping
-  Excessive flatulence (wind)
-  Diarrhoea
-  Constipation
-  Burning sensation in the mouth and/or throat
-  Coughing

8.2 Managing side effects if they occur

Check that **K·Vita** is always being taken at the same time as food and that the plan to introduce it slowly and in measured amounts is being followed. Advise trying one or more of the following to see if tolerance can be improved:

-  If in the first few weeks of the introduction, having a one or two-day break, then restarting from the beginning
-  If in the middle or towards the end of the introduction, reducing the amount taken by going back a day or two in the plan (or to when side effects were first noticed). Then, staying on that daily amount until things improve, and increasing again, according to the introduction plan
-  Making increases more slowly, for example, every two or three days instead of every day

Alternatively, the **K·Vita** Calculator can be used to adjust the plan, for example, to extend the duration from four to six weeks, or to reduce the daily amount being aimed for (**Section 4, Section 5**) <http://vitaflo.co/k-vita-calculator>

GI tolerance to MCT can take time to establish. Amendment of the introduction plan may be required to facilitate this, and encouragement to continue to take **K·Vita** needed before benefits are seen.

Any side effects that do occur are usually mild and tend to disappear with time and or management advice implementation.

The 'Guide for adults and children taking **K·Vita**' advises contacting the healthcare professional if side effects continue after trying these suggestions, and if any other symptoms occur which might be associated with the use of **K·Vita**.

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Support provision and follow-up

1. Provide contact details for access to help with **K·Vita**-related issues
2. Arrange a prescription for **K·Vita** via the GP or the 'Vitaflo to You' home delivery service: www.nestlehealthscience.co.uk/vitaflo/vitaflo-to-you
3. Monitor adherence and efficacy of **K·Vita**:
 - ▮ During and/or at the end of the introduction
 - ▮ On an ongoing basis, as part of routine clinical care
4. Concerns regarding dietary intake and/or nutritional status should be managed by a dietitian



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Management of K·Vita intake during intercurrent illness or surgery

The clinical team caring for the adult or child should advise on continuing or stopping **K·Vita** during an intercurrent illness or before surgery. When restarting **K·Vita**, a slow reintroduction (always with food) back up to their usual daily amount may be required to re-establish GI tolerance to MCT. Progress will be dependent on factors such as the cause, severity and duration of the illness, or the reason for surgery. How the initial introduction of **K·Vita** went may also need to be taken into consideration.

Practical suggestions from the Service Evaluation regarding the reintroduction of **K·Vita** post-illness or after being nil-by-mouth include taking a quarter or a half of the usual daily amount on the first day, then gradually increasing up to the full daily amount over the following two to three days, as tolerated. During this time, dividing **K·Vita** into smaller quantities that are taken more frequently, for example, five or six times daily instead of three or four, can also be helpful.

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Discontinuing K·Vita

If it is decided to discontinue **K·Vita** due to lack of observed benefit or for other reasons, consideration should be given to the clinical condition and circumstances of the individual, how much **K·Vita** they are currently being given, and how long they have been on it for.

Depending on these factors, it can either be stopped straight away or a plan provided to reduce the daily amount gradually, for example, over a few days or a week.

The optimal duration for a patient to take **K·Vita** for the dietary management of drug-resistant epilepsy has yet to be established.

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Storing 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.

Summary

Advising on the use of K·Vita by adults and children in 7 steps:

- 1** Provide the 'Guide for adults and children taking **K·Vita**' and an individualised **K·Vita** introduction plan.
- 2** **IMPORTANT:** Explain the **K·Vita** introduction plan, how to measure **K·Vita** and how to manage any symptoms of GI intolerance, if they occur.
- 3** Explain that **K·Vita** is consumed as part of their usual diet, or their special diet. Provide individual dietary advice, including tips on reducing sugar intake if appropriate.
- 4** Provide contact details for access to support with the introduction of **K·Vita** (as this is an important time) and for its continuing use.
- 5** Arrange for a prescription of **K·Vita** via the GP or '**Vitaflo To You**' www.nestlehealthscience.co.uk/vitaflo/vitaflo-to-you
- 6** **Plan follow-up:** make contact during and/or at the end of the introduction of **K·Vita**, then as part of routine care.
- 7** At follow-up: establish GI tolerance and efficacy to **K·Vita** and advise accordingly. Refer any concerns with dietary intake and/or nutritional status to a dietitian.



References

1. 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 <https://doi.org/10.1093/braincomms/fcab160>
2. Marten B, Pfeuffer M, Schrezenmeir J. Medium-chain triglycerides. International Dairy Journal. 2006 Nov 1; 16(11): 1374-82.
3. Sils 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): 1168-72.0



Food for Special Medical Purposes.
With sweetener.

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 dietitian 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 who cannot metabolise the medium chain fatty acids (C8 and/or C10 fatty acids), for example those with medium chain acyl-CoA dehydrogenase deficiency (MCADD), multiple acyl-CoA dehydrogenase deficiency (MADD) or carnitine cycle defects.

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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