



Healthcare Professional Guide

Enteral Tube Feeding

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



Enhancing Lives Together

Disclaimer

Please read this section very carefully as it contains very important information.

This practical guide about **K·Vita** is intended for use by **qualified healthcare professionals only**.
It is not for use by patients, their parents, or their caregivers.

K·Vita is for use by adults and children from 3 years of age with drug resistant epilepsy. K·Vita is a food for special medical purposes and **must only be used under medical supervision**.

The information in this practical guide is for informational purposes only. It does not constitute nor is a substitute for medical advice provided by an appropriately qualified healthcare professional. Any decision by a healthcare professional to recommend that their patient use **K·Vita** is therefore to be determined entirely by them, using their own professional judgement in all circumstances without any reliance on the information contained in this practical guide.

If you are a patient, or their parent or their caregiver reading this practical guide, likewise, it does not constitute, nor is it a substitute, for medical advice provided by a qualified healthcare professional. You should not use or rely on any information about **K·Vita** contained within it as an alternative to medical advice from your doctor or other healthcare professional whose supervision you are under and with whom you should discuss any aspect of it directly.

Therefore, in the absence of any negligence or other breach of duty by Vitaflo® (International) Ltd, Vitaflo (International) Ltd **does not**, to the fullest extent permitted by law, accept any liability for the incorrect use of **K·Vita** to or by any person.

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

IMPORTANT INFORMATION - FEEDING EQUIPMENT

K·Vita contains medium chain triglycerides (MCT). The use of feeding equipment made from polypropylene (PP), which is widely regarded as chemically resistant to MCT oil and lipid-based emulsions under standard conditions, is advised.

Feeding tubes with a minimum width of 10 French gauge are recommended as **K·Vita** is a thickened liquid.

For further information on the use of **K·Vita** for the dietary management of epilepsy, contact Vitaflo (details on last page) or at www.K-Vita.co.uk

Access resources for the use of **K·Vita** at www.vitaflo-via.com/kvita

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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
- Suitable for enteral tube feeding
- Suitable for oral feeding 'as is', or after mixing into suitable foods or beverages, for example, unsweetened yogurt or plain milk. **Note:** *To ensure consistency in daily intake, it is recommended to give K·Vita via a feeding tube to adults and children on a combination of tube and oral feedings (Section 6.6)*

2

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, Section 8**)
2. During the introduction and once established on **K·Vita**, the daily amount should be divided up into three or four equal portions and given with feed at regular intervals throughout the day, for example, every three to four hours
3. The daily amount of **K·Vita** required depends on individual tolerance and efficacy. For guidance, median daily intakes during the clinical trial for adult were two packs (240ml), and for children, one pack (120ml)¹ (**Section 4**)
4. To help avoid side effects to MCT (**Section 8**), **K·Vita** should not be given on an empty stomach. It is best given slowly and always with some feed
5. **K·Vita** can be given 'as is', part way through or straight after a bolus feed, or whilst pausing or during a continuous feed. If it is mixed with feed or diluted with water, the whole amount should be given (**Section 6.2, Section 6.3**)
6. The feed prescribed before **K·Vita** is started can usually be continued provided individual dietary requirements are met (**Section 6.4, Section 6.5**)
7. The advice provided in this practical guide is based on experience gained from the **K·Vita** clinical trial¹ and real world evidence collected during the **K·Vita** service evaluation, up until the date of publication (see back cover)

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Clinical safety and monitoring

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

During the clinical trial of **K·Vita**, 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 reported¹. Real world evidence collected as part of the service evaluation shows that biochemical monitoring varies.

There is currently insufficient evidence to make specific recommendations regarding biochemical monitoring for those on **K·Vita**, and it is therefore 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 achieved by participants in the clinical trial¹.

The maximum amount of **K·Vita** advised for an adult or child is two packs (240ml) per day. Volumes in excess of this may not be comfortably tolerated (**Section 8**) and/or adversely affect dietary intake and status (**Section 6.5**).

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 tolerance of MCT. Some children may require less than one pack (120ml) per day for efficacy. Others may require more, provided the advised daily maximums of 35% of energy intake and/or two packs, 240ml are not exceeded (see next page).



Children only: Alternatively, **K·Vita** can be prescribed up to a maximum of 35% of daily energy requirements, provided the amount given is tolerated, efficacious, and does not exceed two packs (240ml) per day.

A dietary assessment must be undertaken by a registered dietitian to determine the daily energy requirements of the child. From this, a daily amount to aim for can be determined and an individualised introduction plan created using the **K·Vita** calculator

<http://vitaflo.co/k-vita-calculator> (**Section 5**).

5

Introduction of K·Vita

5.1 Establishing tolerance to K·Vita

MCT is associated with symptoms of gastrointestinal 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 given at first, the amount is built up gradually, and it is always given with some feed (and/or food, if this is also consumed by the patient)³.

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 plan

Experience of use from the service evaluation shows that **K·Vita** can be successfully introduced over four weeks by following a pre-prepared plan, however, some adults and children may require longer. They will need an introduction plan created specifically for them to extend the introduction over, for example, six or eight weeks (**Section 5.3**, **Section 5.4**).

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 to print out or send electronically for caregivers to follow.

The 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 given (three or four times daily). After entering a chosen daily amount of **K·Vita** to be reached at the end of the plan (**Section 4**), a schedule is generated, starting with small quantities of **K·Vita** (5ml or 10ml), and detailing day by day, week by week, how much **K·Vita** to measure out and when to give it.

5.4 Pre-prepared introduction plans

Plans for the introduction of up to one pack (120ml) or up to two packs (240ml) of **K·Vita** over four, six or eight weeks are available at <http://www.vitaflo-via.com/kvita> and as printed copies for caregivers to follow.

5.5 During the introduction of **K·Vita**

Encourage caregivers to follow carefully the introduction plan provided and to keep to the advised amounts to help minimise side effects and establish gastrointestinal tolerance to MCT (**Section 8**).

If an adult or child has side effects to MCT whilst following their **K·Vita** introduction plan, it may be worthwhile making some adjustments to slow down the rate of increase by extending the duration, and/or to reduce the daily amount they are aiming for. Use the **K·Vita** calculator to create an amended plan, or change them over to a longer pre-prepared plan (<http://vitaflo.co/k-vita-calculator> **Section 5.3**, **Section 5.4**).

5.6 Determining individual requirements of **K·Vita**



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

During the introduction, if a lower daily amount than the original aim is found to be efficacious (and/or better tolerated), 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, gastrointestinal tolerance, acceptability and efficacy is advised.

If the daily amount reached is:

-  Tolerated and efficacious, it can be continued
-  Tolerated but no benefit is observed, it may be worthwhile for the adult or child to continue being given this amount of **K·Vita** for an agreed period, for example, six months, to assess if any improvement occurs over time

Alternatively, or if no benefit is experienced over time, try gradually increasing **K·Vita** to a daily amount that is tolerated and efficacious but does not exceed the advised maximum intake (**Section 4**). The **K·Vita** calculator can be used to create a plan for this.

Although it may seem that it will take a while to introduce **K·Vita**, it is time well spent. A slow, careful approach has been found to help minimise MCT associated side effects in both the **K·Vita** clinical trial¹ and service evaluation.

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

6

Practical aspects

6.1 Measuring **K·Vita**

1. Ensure that all feeding equipment is made from a MCT-compatible material such as polypropylene (PP). For example, reusable syringes from ENFit <https://medicina.co.uk/>
2. Shake the pack of **K·Vita** well before use
3. Measure **K·Vita** accurately before giving it to the adult or child. The use of a syringe connector or adapter to help load directly from the pack into a syringe can be easier than transferring it into a measuring beaker and then drawing it up
4. Once opened, recap the unused portion, refrigerate the pack and use the remaining **K·Vita** within 48 hours or 6 hours if kept at room temperature

6.2 Tube feeding regimes

Bolus feeds

Adults and children can be given **K·Vita** to coincide with their usual bolus feeding routine. Identify with the caregiver suitable feed times, or modify the feeding schedule so that **K·Vita** is given at regular intervals during the day, for example, every three or four hours.

Continuous tube feeds

Identify with the caregiver suitable time points, for example, four times each day at three or four hour intervals, when **K·Vita** can be given either whilst the feed is running, or first paused, then resumed afterwards.

6.3 Giving K·Vita down a feeding tube

1. Feeding tubes with a minimum width of 10 French gauge are recommended as **K·Vita** is a thickened liquid
2. **K·Vita** will pass more easily down a feeding tube if it is at room temperature. If stored in the fridge, remove 30 minutes beforehand
3. To help avoid side effects to MCT (**Section 8**), it is best not to give **K·Vita** on an empty stomach, and to always give it slowly
4. **K·Vita** can be given 'as is', part way through or straight after a bolus feed, or whilst a continuous feed is paused or running. If mixed with feed, ensure the whole amount is given. **Note:** *it is not advisable to give K·Vita directly via a PEG-Jejunostomy tube. Always give it mixed with feed*
5. Flush the feeding tube with water first
6. Connect the syringe containing the measured amount of **K·Vita** onto the feeding tube via the medicine port
7. Give **K·Vita** by pushing the syringe plunger downwards using steady, gentle pressure
8. To facilitate easier delivery down the feeding tube, **K·Vita** can be diluted with water. Ensure the full amount is always given
9. After giving **K·Vita**, flush the feeding tube with a minimum of 50ml of water.

6.4 Enteral feeds and K·Vita

The feed prescribed for the adult or child before starting **K·Vita** can usually be continued, provided their individual dietary requirements can be met. This also applies to those on a specialist feed for the dietary management of a medical condition in whom its discontinuation would be contra-indicated, for example, a food allergy (**Section 6.5**).

Real world evidence from the service evaluation shows that **K·Vita** is being included as part of ketogenic diets. For example, those with drug-resistant epilepsy in whom the ketogenic diet was efficacious whilst transitioning back to a normal diet (with or without **K·Vita**). Examples of its 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 enteral feeds

Note: *The daily feed 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** (**Section 6.5**)*

6.5 Meeting dietary requirements

Intakes of energy, protein, micronutrients, and fluid

K·Vita will provide a proportion of daily energy intake. Therefore, to prevent inappropriate weight gain, quantity of enteral feed given before starting **K·Vita** may need to be reduced, or the feed changed to one with a lower energy density.

K·Vita does not contain any protein or micronutrients, and has a low fluid content. Any reduction in the quantity of enteral feed given to account for the energy contribution from **K·Vita** may impact on nutritional and fluid intakes. Supplements may be required to meet estimated nutritional requirements.

Nutritional and dietary assessment

Before an adult or child is given K·Vita, and regularly once they are having it every day, a dietitian must:

1. Determine and monitor energy, nutritional and fluid requirements on an individual basis, and ensure these are being met adequately
2. Define the enteral feed and the requirement for any sources of additional protein and/or micronutrients to meet the unique dietary needs of the adult or child whilst they are given **K·Vita**, and determine the most suitable products for them
3. Provide caregivers with instructions on preparing the enteral feed (with the addition of dietary supplements, as required), and ensuring an adequate fluid intake, both during the introduction of **K·Vita** and once the adult or child is established on their daily amount.

6.6 Combined oral and tube feeding

If food is taken orally in combination with tube feeding, the usual diet can be continued. However, it is recommended to give **K·Vita** via a feeding tube rather than by mouth to ensure that the full amount is consumed.

During the clinical trial¹, guidance was given on reducing foods and beverages high in sugar (especially if consumed regularly), to help optimise the nutritional intakes. This advice may also be relevant to adults and children having food in conjunction with an enteral feed and should be provided on an individual basis. For further information, refer to the 'Guide for adults and children taking **K·Vita**' available at www.vitaflo-via.com/kvita

The 'Guide to giving K·Vita to adults and children who are tube-fed'

The guide contains information and advice for caregivers on:

- ▮ **K·Vita** and what it is for
- ▮ Measuring **K·Vita**
- ▮ Giving **K·Vita** via a feeding tube
- ▮ Following the introduction plan
- ▮ Possible side effects from **K·Vita** and how to manage these
- ▮ Amending the amount of enteral feed whilst introducing **K·Vita** (and food, if on a combination of oral and tube feedings)
- ▮ Storing **K·Vita**

Printed copies of the guide, pre-prepared 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 giving K·Vita every day, it is recommended to discuss the following with caregivers:

1. The information in this guide before they start giving **K·Vita**
2. The **K·Vita** introduction plan the adult or child will be following
3. The importance of always giving **K·Vita** with feed, and ensuring the full amount is given each time
4. What the possible side effects to MCT can be, and what they can do to help manage these, if they occur




8.1 What to look out for

MCT can cause symptoms of gastrointestinal intolerance². However, not everyone who takes **K·Vita** is affected. Building up the amount gradually and always giving it with feed can help to minimise side-effects^{1,3}.

However, some adults and children may experience one or more of the following during the introduction of **K·Vita**, the most likely time for them to occur:





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

If taken orally:

-  Burning sensation in the mouth and/or throat
-  Coughing

8.2 Managing side effects if they occur

Check that **K·Vita** is always given at the same time as some feed and that the plan to introduce it slowly and in measured amounts is being followed. If side effects occur, trying one or more of the following may help improve tolerance to **K·Vita**:

-  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, use the **K·Vita** calculator to adjust the plan, for example, to extend the duration from 4 to 6 weeks, or to reduce the daily amount aimed for (**Section 4, Section 5**) www.vitaflo-via.com/kvita or provide a longer pre-prepared introduction plan

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 keep taking **K•Vita** may be needed before benefits are seen.

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

The 'Guide to giving **K•Vita** to adults and children who are tube fed' advises caregivers to contact a healthcare professional if side-effects continue after trying the suggestions that are in the guide, and if any other symptoms occur they think may be associated with the use of **K•Vita**.

9

Support provision and follow-up

1. Provide contact details to access help and support with **K•Vita** related-issues, especially during the introduction, as this is an important time
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. Ensure caregivers have contact details for the Nutrition Support Team
4. Provide the Nutritional Support Team with details about **K•Vita**, the introduction plan that the adult or child will be following, amends (if required) to the feed, and any requests for changes in feeding equipment or supplies
5. 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
6. Concerns regarding dietary intake and/or nutritional status should be managed by a dietitian



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 some feed) 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** progressed may also need taking 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
- and/or:
- ▮ Dividing the daily amount into smaller quantities that are taken more frequently, for example, five or six times daily instead of three or four

The **K·Vita** calculator can be used to plan a reintroduction <http://vitaflo.co/k-vita-calculator>

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, **K·Vita** 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 an adult or child to take **K·Vita** for the dietary management of drug resistant epilepsy has yet to be established, and if any benefit observed whilst it is taken continues after the product is discontinued.

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.

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

- 1 Provide caregivers with the 'Guide to giving **K·Vita** to adults and children who are tube-fed' and an individualised introduction plan for the adult or child
- 2 **IMPORTANT:** Explain the **K·Vita** introduction plan, how to measure **K·Vita** and give via the feeding tube, and how to manage any symptoms of gastrointestinal intolerance, if they occur
- 3 As required, provide instructions for making adjustments to the adults or child's feed (and food taken orally if combined with tube feeding)
- 4 Provide contact details for access to support with the use of **K·Vita** and the Nutrition Support Team
- 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 towards the end of the introduction of **K·Vita**, and as part of routine care and follow-up. Establish tolerance to and efficacy of **K·Vita** and advise accordingly
- 7 Ensure the combined energy and nutritional intake from the feed and **K·Vita** will meet individual requirements. Refer any concerns with dietary intake and/or nutritional status to a dietitian and/or the Nutritional Support Team

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2. Marten B, Pfeuffer M, Schrezenmeir J. Medium-chain triglycerides. International Dairy Journal. 2006 Nov 1; 16(11): 1374-82.
3. Sills MA, Forsythe WJ, 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



K·Vita®

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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