DEKAs in Cholestatic Liver Disease

All-in-one Multivitamin Food for Special Medical Purposes with Enhanced Absorption for the Dietary Management of Cholestatic Liver Disease

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Callion PHARMA
Decades of Formulation and Clinical Research Experience
Helping Patients Overcome Micronutrient Malabsorption

DEKAs vitamins.com
DEKAs delivery technology has been clinically proven to increase the absorption of fat-soluble vitamins and other lipophilic compounds in conditions of malabsorption such as in cholestatic liver disease and cystic fibrosis.¹,²

DEKAs products for Cholestatic Liver Disease contain the right form of vitamin E

- The use of the special form of vitamin E contained in DEKAs Aqua-E and DEKAs Essential liquid is recommended in Cholestatic Liver Disease (CLD) guidelines.

DEKAs Essential liquid covers all fat-soluble vitamins D, E, K and A in one dose

- The supplementation of vitamin D, E, K and A is recommended in CLD guidelines.

DEKAs Essential liquid offers scalable dosing to better meet individual patient needs.

- The dose needed will depend on the severity of cholestasis in the patient.

DEKAs Aqua-E liquid will be needed to optimize treatment if bodyweight increases.

- The dose of TPGS-vitamin E, unlike those of vitamin A, D and K, is directly related to bodyweight. Therefore DEKAs Aqua-E might need to be added on top of DEKAs Essential liquid as bodyweight increases.

1. D-alpha-tocopheryl polyethylene glycol-1000 succinate also known as tocofersolan or TPGS
5. Registered in The Netherlands and selected EEA countries.
What makes DEKAs special
DEKAs Essential liquid and DEKAs Aqua-E liquid

DEKAs was developed in consultation with independent experts
  • Guided by a liver disease research network with leading experts in the field.

DEKAs is based on a unique - clinically tested - delivery technology
  • The DEKAs delivery technology enhances the absorption of fat-soluble vitamins\(^2\).

DEKAs is guideline compliant
  • The composition of DEKAs incorporates the latest EU consensus guidelines on cholestatic liver disease. \(^1,2\)

DEKAs Essential liquid covers all fat-soluble vitamins
  • Contains vitamin D, E, K, A.

DEKAs eliminates the risk of hypervitaminosis A
  • Most of the vitamin A in DEKAs is given as ß-carotene, which is a precursor to vitamin A and is converted by the body to vitamin A as needed. No risk of hypervitaminosis A.

DEKAs is taste-optimized and contains no paraben, gluten, casein, lactose and GMO
  • DEKAs only contains natural flavors.

Study group: 60 children (6 mo to 20 yr old) with severe cholestasis and vitamin E deficiency who were unresponsive to massive oral doses (70-212 IU/kg day) of vitamin-E.¹

Mean follow-up of 2.5 years.

Results: All children responded with normalization of vitamin E status.

Neurological function, which had deteriorated before entry in the trial, improved in 25 patients, stabilized in 27, and worsened in only 2.

This study¹ shows that products like DEKAs Aqua-E and DEKAs Essential liquid contain a safe and effective form of vitamin E for reversing or preventing vitamin E deficiency during chronic childhood cholestasis.

¹ Sokol RJ, et al, Multicenter Trial of d-α-Tocopheryl Polyethylene Glycol 1000 Succinate for Treatment of Vitamin E Deficiency in Children With Chronic Cholestasis Gastroenterology 1993;104:1727-17351987; 93(5):975-85
How to use DEKAs in clinical practice

- DEKAs should be taken under medical supervision
- Your doctor or dietician has to decide:
  - What form of DEKAs is suitable
  - What dose is appropriate
- Vitamin levels should be measured periodically
- Vitamin levels should guide dosing
Nutritional Information DEKAs Aqua-E & Essential
Will be registered in Benelux, United Kingdom, Germany, Switzerland, Spain, France
Food for Special Medical Purposes. Use only under medical supervision.

<table>
<thead>
<tr>
<th>Product</th>
<th>DEKAs Aqua-E liquid</th>
<th>DEKAs Essential liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>One pack</td>
<td>contains 60 ml</td>
<td>60 ml</td>
</tr>
<tr>
<td></td>
<td>1 ml</td>
<td>1 ml</td>
</tr>
<tr>
<td>Vitamin D₃</td>
<td>IU (μg)</td>
<td>2000 (50)</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>IU (mg)</td>
<td>75 (50)</td>
</tr>
<tr>
<td>Vitamin K</td>
<td>μg</td>
<td>2000</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>IU (μg RE)</td>
<td>834 (250)</td>
</tr>
<tr>
<td>ß-carotene</td>
<td>IU (μg RE)</td>
<td>1666 (1000)</td>
</tr>
</tbody>
</table>

1. 100% D-alpha-tocopheryl polyethylene glycol-1000 succinate or tocofersolan.
2. RE = all trans retinol equivalent. ß-carotene is a precursor to vitamin A, and is converted by the body to vitamin A as needed.
Product information

Product information DEKAs Aqua-E liquid: DEKAs Aqua-E liquid, food for special medical purposes. For the dietary management of patients with cholestatic liver disease. DEKAs Aqua-E is a unique, patented, water-soluble vitamin E formulation. Clinical testing has shown that the formulation of DEKAs Aqua-E increases the absorption of vitamin E in patients with malabsorption, such as patients with cholestatic liver disease. Important notice: Use only under medical supervision. Cannot be used as a sole source of nutrition. Can be used by infants, children and adults. The product poses a health hazard if consumed by persons who do not have the disease(s), disorder(s) or medical conditions for which the product is intended. Use in patients with significant renal insufficiency, vitamin K deficiency or taking oral vitamin K antagonists, or during pregnancy, only after consultation with a doctor. Do not use in newborn preterm infants. Use and storage: Shake well before each use. Take directly or mix it with a beverage. Do not use if the seal is broken or missing. Keep out of reach of children. Store at room temperature. Use within 60 days of opening. Recommended dosage: 1 ml (50 mg/75 IU of vitamin E) per 3 kg of body weight per day or as directed by a physician. Dosing should be guided by serum vitamin levels. Allergens: none.

Ingredients: water, D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS), acidulant (citric acid), preservatives (potassium sorbate, sodium benzoate), linoleic acid.

Product information DEKAs Essential liquid: DEKAs Essential liquid, food for special medical purposes. For the dietary management of patients with cholestatic liver disease. DEKAs Essential liquid is a multivitamin supplement that contains higher amounts of fat-soluble vitamins. DEKAs Essential liquid utilizes a clinically tested delivery technology to enhance absorption of fat-soluble vitamins and nutrients. Important notice: Use only under medical supervision. Cannot be used as a sole source of nutrition. Can be used by infants, children and adults. The product poses a health hazard if consumed by persons who do not have the disease(s), disorder(s) or medical conditions for which the product is intended. Use in patients with significant renal insufficiency, taking oral vitamin K antagonists, or during pregnancy, only after consultation with a doctor. Do not use in newborn preterm infants. Use and storage: Do not use if the seal is broken or missing. Keep out of reach of children. Store at room temperature. Use within 60 days of opening. Recommended dosage: 0,5 ml (infants)-1 ml daily or as directed by physician. Dosing should be guided by serum vitamin levels. Take with meals. Shake well before use. Allergens: none.

Ingredients: water, D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS), beta-carotene, acidulant (ascorbic acid), cholecalciferol, phytomenadione, natural and artificial flavors, preservatives (potassium sorbate, sodium benzoate), retinyl palmitate, antioxidant (tocopherol-rich extract), sweetener (sucralose).

Distribution EU
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