

DEKAs in Cystic Fibrosis

All-in-one Multivitamin & Mineral Dietary Supplement with Enhanced Absorption

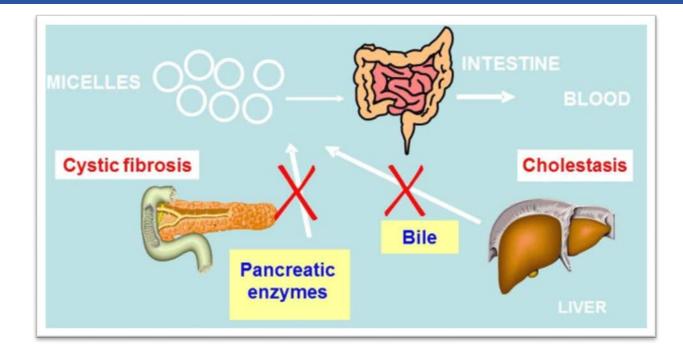
Roberto Jongejan, MD, PhD Gus Papas, MD, MPH





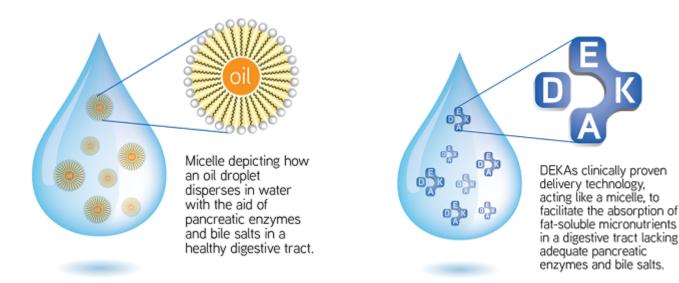
Decades of Formulation and Clinical Research Experience Helping Patients Overcome Micronutrient Malabsorption

Vitamin Malabsorption in Cystic Fibrosis



In cystic fibrosis, pancreatic insufficiency and a diminished bile acid pool lead to malabsorption and deficiencies of fat-soluble vitamins such as vitamins D, E, K and A. These vitamin deficiencies can lead to significant morbidity in cystic fibrosis patients, especially as they are living longer.

DEKAs/AquADEKs Micellar Delivery Technology Clinically studied^{1,2}





1.

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 cholestastic liver disease and cystic fibrosis.^{1,2}

DEKAsvitamins.com

Papas K, Kalbfleisch J, Mohon R, DOI 10.1007/s10620-006-9489-2

2. Argao E, Heubi JE, Hollis BW, et al., DOI: 10.1203/00006450-199202000-00011

DEKAs Product Concept

Registered as Food for Special Medical Purposes* Use under medical supervision

DEKAs provides in <u>one serving</u>:

- 1. Complete coverage of doses of fat-soluble vitamins as recommended in CF guidelines
- 2. Standard doses of water soluble vitamins, minerals and anti-oxidants

DEKAs Plus provides all the vitamins A,B,C,D,E,K, zinc, selenium and anti-oxidants in:

- 1. DEKAS Plus liquid for infants and children up to 4 years of age
- 2. DEKAs Plus softgels and chewable tablets for children 4 years of age and older and adults

DEKAs Essential is for dose titration or stand alone use

- 1. DEKAs Essential can be used if adequate serum levels of fat soluble vitamins are not obtained with DEKAs Plus softgels or chewable tablets..
- 2. DEKAs Essential allows for the titration of vitamins D, E, K, and A, without increasing the dose of water soluble vitamins, minerals and antioxidants
- 3. DEKAs Essential can also be used as a stand-alone fat-soluble vitamin replacement

DEKAs® replaces AquADEKs® in Europe**

The DEKAs house is built on solid principles

Guideline compliant

Contains the right starting dose of vitamins D,E,K, A according to Cystic Fibrosis guidelines^{1,2}



- 1. Sermet-Gaudelus I, et al., European cystic fibrosis bone mineralisation guidelines. J Cyst Fibros 2011;10(2):S16–23.
- Turck D, et al., ESPEN-ESPGHAN-ECFS guidelines on nutrition care for infants, children, and adults with cystic fibrosis, Clinical Nutrition 2016;35(3): 557–577, <u>http://dx.doi.org/10.1016/j.clnu.2016.03.004</u>
 - 3. Netherlands Food and Consumer Product Safety Authority, record numbers <u>9572070/7273 (liquid)</u> and <u>9572075/7274 (softgels)</u>.
 - 4. GMP: Good Manufacturing Practice. Internationally recognized quality standard.
 - 5. GMO: Genetically Modified Organism.

What makes DEKAs special

CLINICALLY TESTED DELIVERY TECHNOLOGY AquADEKs / DEKAs was developed in consultation with independent experts

- Funded by US Cystic Fibrosis Foundation (CFF) and US National Institutes of Health (NIH)
- Guided by a Project Advisory Group that included 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 and micronutrients

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 guideline compliant

 The composition of DEKAs incorporates the latest EU consensus guidelines on nutritional care and bone mineralization in CF^{1,2}

DEKAs covers all vitamin bases and is anti-oxidant rich

- In addition to fat-soluble vitamins DEKAs Plus contains water-soluble vitamins and minerals in levels often found in standard multivitamin mineral supplements. So all bases are covered
- DEKAs contains high levels of antioxidants, as antioxidants can run low in chronic inflammation.

DEKAs is taste-optimized

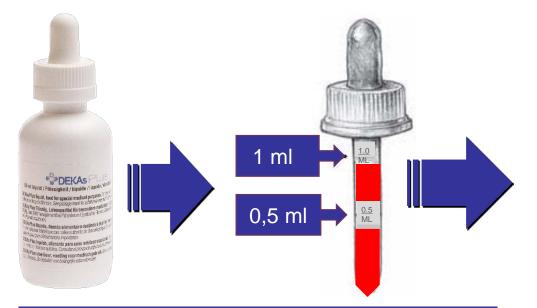
DEKAs is based on natural flavors and the liquid contains taste-masking technology.

Sermet-Gaudelus I, et al., European cystic fibrosis bone mineralisation guidelines. J Cyst Fibros 2011;10(2):S16-23. 1.

2. Turck D, et al., ESPEN-ESPGHAN-ECFS guidelines on nutrition care for infants, children, and adults with cystic fibrosis, Clinical Nutrition. 2016;35(3): 557-577, http://dx.doi.org/10.1016/j.clnu.2016.03.004

DEKAs Plus Liquid – how to give

Strong orange color – taste of sweet peach/orange juice – take with meal







- 1. Syringe it to the side of the mouth.
- 2. Mix in a small bottle.
- 3. When all else fails we mix it with a little put of apple sauce and spoon it in.

(caregiver on internet)



- https://www.**youtube**.com/watch?v=o-p7AjxM3KY
- https://www.youtube.com/watch?v=rjgAgn8V-cl

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

Registered in Benelux, United Kingdom, Germany, Switzerland, Spain, France Food for Special Medical Purposes. Use only under medical supervision.

Product		DEKAs Plus softgels	DEKAs Plus chewables	DEKAs Essential capsules	DEKAs Plus liquid	
One pack contains		6o softgels	6o chewables	60 capsules		
		1 softgel	1 chewable	1 capsule	1 ml	2ml
Vitamin A	IU (μg RE)*	1500 (450)	1500 (450)	500 (150)	750 (225)	1500 (450)
ß-carotene	IU (mg RE)*	16667 (10)	16667 (10)	1500 (0,9)	5001 (3)	10002 (6)
Vitamin D ₃	IU (μg)	3000 (75)	2000 (50)	2000 (50)	750 (18,8)	1500 (37,5)
Vitamin E	IU (mg)	150 (101)	100 (101)	150 (101)	50 (33,6)	100 (67,2)
Vitamin K	μg	1000	1000	1000	500	1000
Thiamin (B1)	mg	1,5	1,5		0,6	1,2
Riboflavin (B2)	mg	1,7	1,7		0,6	1,2
Niacin	mg	10	10		6	12
Vitamin B6	mg	1,9	1,9		0,6	1,2
Folic acid	μg	200	200		-	
Vitamin B12	μg	12	12		-	
Vitamin C	mg	75	70		45	90
Biotin	μg	100	100		15	30
Pantothenic Acid	mg	12	12		3	6
Zinc	mg	10	10		5	10
Selenium	μg	75	75		10	20
Co-enzyme Q10	mg	10	10		2	4
* RE = all trans retinol equivalent. B-carotene is a precursor to vitamin A, and is converted by the body to vitamin A as needed.						

Product information

Product information DEKAs Plus softgels / DEKAS Plus chewable tablets / DEKAs Essential capsules: DEKAs Plus softgels / DEKAs Plus chewable tablets / DEKAs Essential capsules; food for special medical purposes. For the dietary management of patients with cystic fibrosis where serum levels of fat-soluble vitamins cannot be normalized with regular food supplements. DEKAs Plus/Essential is a multivitamin and mineral supplement that contains higher amounts of fat-soluble vitamins. DEKAs Plus/ Essential 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 from the age of 4 years. The product poses a health hazard if consumed by persons who do not have the disease (s), disorder(s) or medical condition(s) for which the product is intended. Use during pregnancy and/or combined use with anticoagulants only after consultation with a doctor. **Use and storage:** Do not use if the seal is broken or missing. Keep out of reach of children. Store at room temperature. **Recommended dosage:** Age 4 to 10 years: 1 softgel / 1 chewable tablet / 1 capsule daily or as directed by physician. Over age 10: 1-2 softgels / 1-2 chewable tablets / 1-2 capsules per day as directed by a physician. Take with meals. **Allergens:** none.

Ingredients DEKAs Plus softgels: capsule (bovine gelatin, humectants: E422, E420; colorants: E150d, E171, flavouring: ethylvanillin), soybean oil, D-alphatocopheryl polyethylene glycol-1000 succinate, antioxidant (tocopherol-rich extracts), sodium ascorbate, D-alpha-tocopherol, selenium enriched yeast, beta-carotene, zinc sulphate, calcium D-pantothenate, nicotinamide, D-biotin, coenzyme Q10, cholecalciferol, pyridoxine hydrochloride, thiamin mononitrate, riboflavin, cyanocobalamin, retinyl palmitate, phytomenadione, folic acid.

Ingredients DEKAs Plus chewable tablets: sugar, dextrose, natural flavors, sodium-L-ascorbate, sweetener (sorbitol), bulking agent (hydroxypropylcellulose), beta-carotene, D-alphatocopherol, anti-caking agent (calcium silicate), flavor (citric acid), zinc bisglycinate, nicotinamide, cholecalciferol, phytomenadione, D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS), calcium D-pantothenate, anti-caking agent (magnesium stearate), D-biotin, coenzyme Q10, pyridoxine hydrochloride, retinyl palmitate, sodium selenite, thiamin mononitrate, riboflavin, sweetener (sucralose), anti-caking agent (silicon dioxide), cyanocobalamin, antioxidant (tocopherol rich extract), folic acid.

Ingredients DEKAs Essential capsules: D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS), D-alpha-tocopherol, capsule (tilapia fish gelatin, water), beta-carotene, cholecalciferol, phytomenadione, retinyl palmitate.

Product information DEKAs Plus liquid: DEKAs Plus liquid, food for special medical purposes. For the dietary management of patients with cystic fibrosis. DEKAs Plus is a multivitamin and mineral supplement that contains higher amounts of fat-soluble vitamins. DEKAs Plus utilizes a clinically tested delivery technology to enhance absorption of fat-soluble vitamins and nutrients. **Important notice:** For children from o-3 years of age. Use only under medical supervision. Not for parenteral use. Cannot be used as a sole source of nutrition. 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 during pregnancy and/or combined use with anticoagulants only after consultation with a doctor. **Use and storage:** Do not use if the seal is broken or missing. Shake well before use. Keep out of reach of children. Store at room temperature. Refrigerate after opening. **Recommended dosage:** Age o to 12 months: 1 ml daily. Age 1-3 years: 2ml daily. Or as directed by physician. **Allergens:** none.

Ingredients DEKAs Plus liquid: water, L-ascorbic acid, sodium-L- ascorbate, D-alpha-tocop glycol-1000 succinate, zinc gluconate, beta-carotene, D-alpha-tocopherol, antioxidant (tocopherol-rich extracts), nicotinamide, natural and artificial flavors, calcium D-pantothenate, sweetener (sucralose), coenzyme Q10, thiamin hydrochloride, riboflavin 5'- phosphate sodium, cholecalciferol, pyridoxine hydrochloride, retinyl palmitate, preservatives (potassium sorbate, sodium benzoate), phytomenadione, sodium selenite, D-biotin.

Distribution EU

DEKAsvitamins.com • Platolaan 71 • 3707 GD Zeist • Netherlands • T +31621255794 <u>info@dekasvitamins.com</u> • <u>www.dekasvitamins.com</u> is a registered trade name of Alveolus Biomedical B.V.

Distribution Switzerland

Apotheke zum Rebstock • Grundstrasse 4 • CH-8712 Stäfa • Switzerland • info@apothekezumrebstock.ch

Manufactured in the USA for

Callion Pharma • 232 Presidential Drive • Suite 7 • Jonesborough • TN 37659 • USA • www.callionpharma.com