



VSL#3[®]

THE LIVING SHIELD[®]

PRODUCT INFORMATION SHEET

VSL#3[®] is a probiotic medical food intended for the dietary management of Irritable Bowel Syndrome (IBS), Ulcerative Colitis (UC) or an ileal pouch.

Description

VSL#3[®] is a potent probiotic medical food specially formulated to provide a mixture of live, freeze-dried lactic acid bacteria and bifidobacteria per packet or capsule. VSL#3[®] is available in 3 different concentrations:

- a) VSL#3[®] Capsules: 112.5 billion CFU* per capsule
- b) VSL#3[®] Unflavored: 450 billion CFU* per packet
- c) VSL#3[®] Double Strength (DS): 900 billion CFU* per sachet

*CFU, colony-forming units.

VSL#3[®] products are manufactured in accordance with Current Good Manufacturing Practice for foods, using ingredients that have been approved by the U.S. Food and Drug Administration (FDA) as food additives or are "Generally Recognized as Safe" (GRAS) for their intended use.

Directions

VSL#3[®] can be mixed with any cold, noncarbonated beverage and then consumed. VSL#3[®] can also be mixed into any cold food such as yogurt, ice cream, or applesauce, and then consumed. Heated beverages are not recommended because exposure to heat and moisture may reduce bacterial viability and activity. VSL#3[®] should be taken as directed by a physician. Adjustment of the intestinal flora can take a few days or weeks; it may take up to 1 month for the colonization of the gut to become optimally stable.

Strains of bacteria

- *Streptococcus thermophilus*
- *Bifidobacterium breve*
- *Bifidobacterium longum* (reclassified as *B. lactis*)
- *Bifidobacterium infantis* (reclassified as *B. lactis*)
- *Lactobacillus acidophilus*
- *Lactobacillus plantarum*
- *Lactobacillus paracasei*
- *Lactobacillus delbrueckii* subsp. *bulgaricus* (reclassified as *L. helveticus*)

All ingredients

- a) VSL#3[®] Capsules: Lactic acid bacteria and bifidobacteria blend, hydroxypropylmethylcellulose, cornstarch, magnesium stearate, silicon dioxide, stearic acid, microcrystalline cellulose.
- b) VSL#3[®] Unflavored packets: Lactic acid bacteria and bifidobacteria blend, cornstarch, silicon dioxide.
- c) VSL#3[®] DS sachets: Maltose, lactic acid bacteria and bifidobacteria blend, cornstarch, silicon dioxide.

Allergen Status

All formulations of VSL#3[®] contain none of the following: wheat, gluten (other cereals), soy, milk including lactose, crustacean shellfish, eggs, peanuts, nuts, fish, celery, mustard, sesame seeds, sulfur dioxide and sulfites (>10 mg/kg), lupin, mollusks. VSL#3[®] contains cornstarch, an inactive ingredient, which is generally well-tolerated.

GMO Status

All formulations of VSL#3[®] do not consist of, nor contain, nor are produced from genetically modified organisms according to the definitions of Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003 of the European Parliament and the Council of 22 September 2003.

All formulations of VSL#3[®] are Kosher and Halal-certified.

Probiotic Medical Food

As a probiotic medical food, VSL#3[®] is specifically formulated and processed to be consumed by oral intake under the supervision of a physician and is intended for the dietary management of individuals with IBS, UC and a ileal pouch, which present distinctive nutritional requirements which cannot be adequately managed through dietary modification alone of the normal diet.

VSL#3[®] is a medical food and must be used under medical supervision.

Interactions with other medications

VSL#3[®] is believed to be compatible with most types of drugs. If taken with antibiotics, VSL#3[®] should be consumed in-between antibiotic doses thereby maximizing the probiotic effect.

Side Effects

Mild abdominal bloating has been reported in the first few days of consuming VSL#3[®]. This is usually a transitory phenomenon due to the changing intestinal microflora. If you experience bloating, you may need to reduce your daily intake to allow for this adjustment. Please report any unexpected reaction after starting VSL#3[®] to Alfasigma USA, Inc. by calling (toll free) (866) 634-2765.

Precautions

Please keep this product out of reach of children. Pregnant or lactating women should consult with a physician or healthcare professional before using this or any other medical food product.

Table 1: Adult Recommended Daily Intake

For the Dietary Management of	VSL#3 [®] Capsules (112.5 Billion CFU/ capsule)	VSL#3 [®] Unflavored (450 Billion CFU/pkt)	VSL#3 [®] DS (900 Billion CFU/ sachet)
Irritable bowel syndrome	4-8 (450-900)	1-2 (450-900)	N/A
Ulcerative colitis (maintenance)	8-16 (900-1800)	1-2 (450-900)	N/A
Pouchitis	N/A	2-4 (900-1800)	1-2 (900-1800)
Active ulcerative colitis (flaring)	N/A	4-8 (1800-3600)	2-4 (1800-3600)

CFU, colony-forming units; N/A, not applicable.

Table 2: Pediatric Recommended Daily Intake

Recommended intake by age (in years)	Dietary Management of active (flaring) ulcerative colitis (Billion CFU)		
	VSL#3 [®] Capsules	VSL#3 [®] Unflavored	VSL#3 [®] DS
≤ 5	1-2 (112-225)	N/A	N/A
6-11	4-8 (450-900)	1-2 (450-900)	N/A
12-17	8-16 (900-1800)	2-4 (900-1800)	1-2 (900-1800)
Recommended intake by age (in years)	Dietary Management (maintenance) of ulcerative colitis (Billion CFU)		
	VSL#3 [®] Capsules	VSL#3 [®] Unflavored	VSL#3 [®] DS
≤ 5	1-2 (112-225)	N/A	N/A
6-11	2-4 (225-450)	0.5-1 (225-450)	N/A
12-17	4-8 (450-900)	1-2 (450-900)	0.5-1 (450-900)
Recommended intake by age (in years)	Dietary Management of Irritable Bowel Syndrome (Billion CFU)		
	VSL#3 [®] Capsules	VSL#3 [®] Unflavored	
≤ 5	1-2 (112-225)	N/A	
6-11	2-4 (225-450)	0.5-1 (225-450)	
12-17	4-8 (450-900)	0.5-2 (225-900)	

CFU, colony-forming units; N/A, not applicable.

Storage

VSL#3[®] consists of live, lyophilized bacteria. It should be stored at a cold and stable temperature. VSL#3[®] products if unopened and stored under refrigeration (36-46°F or 2-8°C), are guaranteed through the "Best if used by" date. VSL#3[®] can be stored at room temperature (77°F) for up to 2 weeks without having a major effect on potency. If it is left at room temperature for longer periods of time or exposed to excessive heat, the number of beneficial bacteria in VSL#3[®] can become greatly reduced. Studies have not been conducted on the effects of freezing on VSL#3[®]. But repeating changes in temperature such as freezing, refrigerating and refreezing can stress the bacterial cell membranes, which are vital to the life of the bacteria. Therefore, VSL#3[®] can be stored until needed in the freezer, but once it has been frozen and then thawed, it should then be maintained at refrigeration temperature and not be refrozen.

How Supplied

SKU (Single keeping Unit)	Units per box or bottle	UPC
VSL#3 [®] Capsules	60 capsules	7-45749-01781-9
VSL#3 [®] Unflavored	30 packets	7-45749-01780-2
VSL#3 [®] DS	20 sachets	7-45749-01782-6

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