**VSL#3®**

**THE LIVING SHIELD**

**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 mix of live, freeze-dried lactic acid bacteria and bifidobacteria per packet or capsule. **VSL#3®** is available in 3 different concentrations:

- **VSL#3® Capsules**: 112.5 billion CFU* per capsule
- **VSL#3® Unflavored**: 450 billion CFU* per packet
- **VSL#3® Double Strength (DS)**: 900 billion CFU* per sachet of 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, non-carbonated 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.
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**All ingredients**

- **VSL#3® Capsules**: Lactic acid bacteria and bifidobacteria blend, hydroxypropylmethylcellulose, cornstarch, magnesium stearate, silicon dioxide, ascorbic acid, microcrystalline cellulose.
- **VSL#3® Unflavored packets**: Lactic acid bacteria and bifidobacteria blend, cornstarch, silicon dioxide.
- **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) 1801/2003 of the European Parliament and the Council of 23 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 adults with IBS, UC and an ileal pouch, which presents distinct 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 microbiota. 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 Allergena USA, Inc. by calling toll-free (866) 634-2785.

**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.

**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 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**

- **VSL#3® Capsules**: 112.5 billion CFU* per capsule
- **VSL#3® Unflavored packets**: 450 billion CFU* per packet
- **VSL#3® Double Strength (DS) sachets**: 900 billion CFU* per sachet

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

**Table 1: Adult Recommended Daily Intake**

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>Amount per day (CFU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsules</td>
<td>225 billion</td>
</tr>
<tr>
<td>Unflavored</td>
<td>900 billion</td>
</tr>
<tr>
<td>DS Sachets</td>
<td>2700 billion</td>
</tr>
</tbody>
</table>

**Table 2: Pediatric Recommended Daily Intake**

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>Amount per day (CFU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsules</td>
<td>112.5 billion</td>
</tr>
<tr>
<td>Unflavored</td>
<td>450 billion</td>
</tr>
<tr>
<td>DS Sachets</td>
<td>900 billion</td>
</tr>
</tbody>
</table>

**GMP and Date Code**

**VSL#3®** is 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.

**Date Code**

The date code indicates the “Best if used by” date of the product when properly stored. The Useful Life of the product is limited to the “Best if used by” date or the shelf-life of the dry product, whichever is reached first. **VSL#3®** should be kept out of reach of children and should not be used if the package shows signs of tampering or damage.