



About Eligen B12™

Eligen B12™ is an oral, prescription medical food* tablet indicated for the dietary management of patients who have a diagnosed vitamin B12 deficiency, associated with a disease or condition, that cannot be managed by a modification of the normal diet alone.

Dosage and Administration

- Each Eligen B12 tablet contains cyanocobalamin 1000 mcg/salcaprozate sodium (SNAC) 100 mg for use under supervision of a physician
- Initial dose of vitamin in Eligen B12 for all patients is 1000 mcg cyanocobalamin daily
- Physicians may titrate to an effective dose, up to a maximum of 2 tablets (2000 mcg) daily

How It Works

Eligen B12 uses innovative technology to enable B12 absorption directly into the bloodstream independent of intrinsic factor, a protein made in the stomach that normally facilitates B12 absorption.

- Eligen® technology utilizes a carrier, salcaprozate sodium (SNAC), to chaperone B12 through the gastric lining and directly into the bloodstream, facilitating the vitamin's absorption.
- Once Eligen B12 crosses the gastric lining and reaches the intracellular space the carrier detaches, leaving the B12 free to pass directly to the bloodstream. The inactive carrier is then excreted.

Indications and Usage

Eligen B12 is indicated for the dietary management of patients who have a diagnosed vitamin B12 deficiency, associated with a disease or condition, that cannot be managed by a modification of normal diet alone. This deficiency can be caused by a range of conditions in which there is an impaired capacity to absorb the vitamin, such as:

1. Pernicious anemia – the malabsorption of B12 because of a deficiency of intrinsic factor resulting from lesions that damage the gastric mucosa, or from diseases associated with gastric atrophy.
2. Malabsorption of vitamin B12 resulting from structural or functional damage to the ileum, where intrinsic factor facilitates vitamin B12 absorption.
3. Competition for vitamin B12 by intestinal parasites or bacteria.
 - a. The fish tapeworm (*Diphyllobothrium latum*) absorbs large quantities of vitamin B12 and infested patients often have associated gastric atrophy.
 - b. Blind loop syndrome may produce deficiency of vitamin B12.
4. Inadequate utilization of vitamin B12. This may occur if antimetabolites for the vitamin are employed in the treatment of neoplasia.

Eligen B12 is not indicated for vitamin B12 supplementation in healthy patients.

**Note: A prescription medical food is an FDA product classification. Medical foods are formulated to be consumed or administered orally under medical supervision and are intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation.*

Clinical Studies

- In a study that compared the impact of Eligen B12 and IM B12 on plasma B12 levels in 50 patients with demonstrated B12 deficiency (serum B12 <350 pg/mL) both products normalized B12 levels by Day 15 (first observation) and maintained normal levels over the duration of the study (three months).ⁱ
- Eligen B12 effectively reduced MMA and homocysteine levels, high levels of which are recognized as precursors to B12 deficiency. When MMA and homocysteine levels were compared between Eligen B12 and IM B12 subjects, MMA and homocysteine levels were similarly decreased in both study groups.ⁱ
- In a study that compared bioavailability in 20 healthy subjects of Eligen B12 with that of a standard oral B12 preparation, the bioavailability of Eligen B12 was 5.09 percent compared with 2.16 percent, which is more than double the bioavailability of the conventional over-the-counter oral B12 formulation at the same dose.ⁱⁱ

Eligen B12 Safety Profile

- Those with an allergy to B12, cobalt or any ingredients of Eligen B12 should not take this product.
- Eligen B12 should not be taken by people who have Leber's disease, which physicians may refer to as hereditary optic nerve atrophy. Cyanocobalamin (B12) can lead to optic nerve damage (and possibly blindness) in people with Leber's disease.
- Note that Eligen B12 has not been studied in patients below 18 years of age.

Adverse Reactions

- No specific adverse reactions were identified during limited studies with Eligen B12. Adverse reactions noted with other B12 formulations are:
 - Generalized: Anaphylactic shock and death
 - Cardiovascular: Pulmonary edema and congestive heart failure early in treatment; peripheral vascular thrombosis
 - Hematological: Polycythemia vera
 - Gastrointestinal: Mild transient diarrhea
 - Dermatological: Itching; transitory exanthema
 - Miscellaneous: Feeling of swelling of entire body

SOURCE: Eligen B12 package insert

ⁱ Emisphere Technologies Inc. Eligen B12 white paper sales aid. Roseland, NJ. Accessed 2014

ⁱⁱ Pharmacokinetics of Oral Cyanocobalamin Formulated With Sodium N-[8-(2-hydroxybenzoyl) amino]caprylate (SNAC): An Open-Label, Randomized, Single-Dose, Parallel-Group Study in Healthy Male Subjects. M. Cristina Castelli et. al. *Clinical Therapeutics*/Volume 33, Number 3, 2011.