designs for health® Australia

Liposomal Methyl B12

Bioavailable Methyl B12 using liposomal technology for optimal absorption and delivery

285 microlitres = 1 spray

OVERVIEW

- Provides 1000 mcg of Methyl B12 (mecobalamin) per 1 spray
- New innovative proprietary Liposomal Technology for optimal absorption and delivery
- Assists in decreasing homocysteine levels when dietary intake is inadequate
- Supports energy levels
- Maintains nervous system function
- Maintains immune system function
- Relieves fatigue

Active Ingredients (per 285 microlitres – 1 spray)	
Mecobalamin	1000 micrograms

Pack Size	50 mL
Serving Per Pack	175 sprays

Excipients

Purified water, Sunflower lecithin (equiv. phospholipids 40.3 mg/g), Raspberry juice concentrate, Tocofersolan, Glycerol, Ethanol.

Directions for Use

Take 285 microlitres (1 spray) daily by mouth or as directed by your health care professional. Spray directly into the inner cheek or under the tongue and hold in the mouth for 30 seconds before swallowing. Take on an empty stomach.

Allergen Information

Does not contain: soy, gluten, dairy, lactose or nuts

Prescribing Considerations

General Safety

- Vitamin B12 is generally considered safe, even in large doses.
- Considered safe in pregnancy and breastfeeding with normal intake.

Cautions and Contraindications

- Vitamin B12 may occasionally cause diarrhoea and itching skin. Signs of polycythemia vera may be unmasked.
- Mega doses may exacerbate acne.

Interactions

- Many drugs reduce absorption of vitamin B12.
- Alcohol – excessive intake may reduce the absorption of vitamin B12.
- Metformin may reduce absorption of vitamin B12.
- Methyldopa may reduce absorption of vitamin B12.
- Oral contraceptives may reduce blood levels of vitamin B12.
- Proton pump inhibitors – long term therapy may reduce serum vitamin B12 levels.

Nutrients

- Folic acid – large doses given continuously may reduce vitamin B12 in blood.
- Vitamin C may destroy vitamin B12 (avoid large doses of vitamin C within 1 hour of oral vitamin B12).

Warnings

- Contains ethanol 12%.
- Vitamin supplements should not replace a balanced diet.
- If symptoms persist talk to your health professional.

Designed and packed in Australia from imported ingredients.

No Added Soy

No Added Gluten

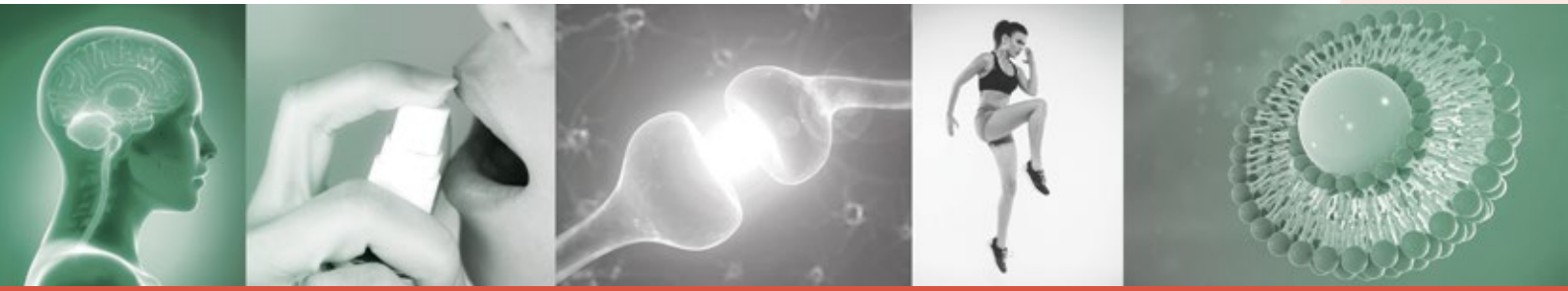
No Added Dairy

No Added Nuts

No Added Shellfish

No Added Yeast

Vegan Friendly

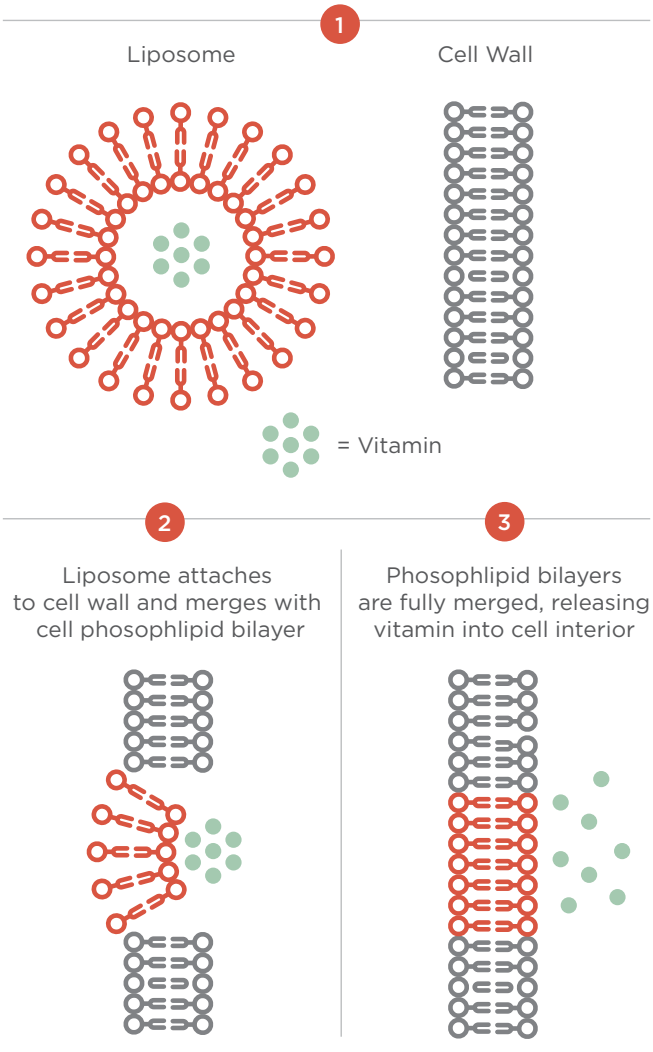


EDUCATION

Liposome structure and function

A liposome is a vesicle made up of at least one phospholipid bilayer, which can be used to deliver hydro- or lipophilic drugs into the cell. The liposome vesicle's phospholipid bilayer merges with the phospholipid bilayer of the cell wall, releasing the nutrient into the cell interior (see Figure 1).

Figure 1: Liposomal Vitamin merging onto cell wall.



Liposomes can range in size, with smaller vesicles giving greater absorption and cellular uptake, being cleared at a slower rate giving greater opportunity for absorption, and being able to be absorbed from the buccal cells meaning they get to the cell more quickly than waiting for absorption into the bloodstream from the stomach. The liposomes in Designs for Health products are 50-100nm in size.[7]

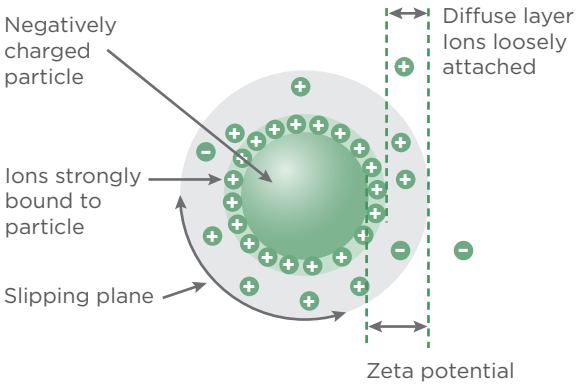
Liposomal Quality – particle size is not the whole story

Zeta potential

One of the key physicochemical properties that determine liposomal quality is the integrity and structure of each liposomal sphere. If the sphere fails, the medicine within the liposome can leak, rendering the liposome ineffective.[8]

One way to monitor the integrity of the spheres to ensure medicine retention is to measure the net charge or "zeta potential".[8]

Zeta potential is defined as the electrical charge between the outer edge of the sphere the slipping plane) and the free water molecules/ions surrounding the outer edge of the sphere. If the ions on the edge and the free ions both have a similar electrical charge (for instance, both positive), a repulsive force is created (like that created when two batteries are placed side by side with their positive ends facing one another). This force keeps the sphere formation intact.[9]



Zeta potential measurement[9]

Low Zeta potential is an indication that the integrity of the sphere is compromised and that the liposomal medicine has become an emulsion. The higher the zeta potential, the greater the stability and integrity of the liposome. See Figures 2 and 3.

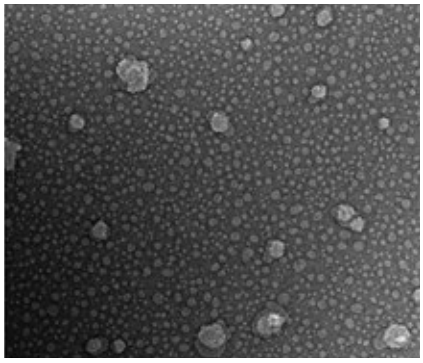


Figure 2:
Liposomal Medicine with spheres intact. Zeta potential = negative 34eV (Designs for Health Liposomal D3).

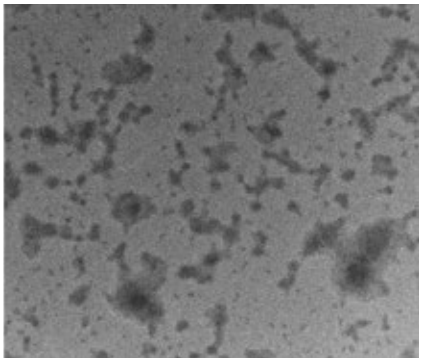


Figure 3: Liposomal medicine with spheres compromised. Zeta potential = negative 14 eV.

From the above, it also becomes obvious that the presence of water is critical to creating a stable liposomal formulation.

Each batch of Designs for Heath Liposomal products is tested for zeta potential upon release and then throughout the shelf-life of the product to ensure the superior quality of our Liposomals.

Benefits of liposomal delivery[10]

- Facilitates absorption in the buccal cells
- Facilitates gastrointestinal uptake
- Prevents breakdown by stomach acid
- Able to incorporate both hydro- and lipophilic agents
- Reduces risk of side effects
- Increased circulation time with smaller nanoparticles (inverse relationship between particle size and clearance time)
- Increased absorption with smaller particle size (9-fold increase from 236nm to 97nm and 34-fold higher at 64nm)
- Increased patient compliance for those who cannot or prefer not to swallow tablets
- Increased ability for flexible dosing

Immune system support

Ascorbic acid (vitamin C) is commonly linked to the immune system. *In vitro*, vitamin C has been shown to effect production and function of neutrophils, lymphocytes and phagocytes.[3] Vitamin C is also protective for these leukocytes, neutralising the reactive oxygen species (ROS) released by leukocytes to kill pathogens before they can damage healthy endogenous cells.[3]

Other *In vitro* studies have shown vitamin C to support interferon production – a type of cytokine with an antiviral effect.[3]

For daily immune system support, vitamin C intake should be at a level which maintains or saturates plasma levels – 100-200mg per day minimum – while intake during infection should be considerably higher to meet the increased demand.[4]

Homocysteine reduction

"Methylcobalamin aids in the conversion of homocysteine to methionine by the action of methionine synthase, transferring a methyl group from methylfolate (folic acid). After conversion from homocysteine, methionine is then converted to S-adenosyl-L-methionine (SAME), which is important for methylation reactions and protein synthesis".[1]

Studies have shown supplementation of methylcobalamin leads to a reduction in homocysteine levels when dietary levles of B12 aren't adequate. *Yajnik et al.* showed that supplementation of 500mcg of methylcobalamin significantly decreased homocysteine by 38% in as little as two weeks; comparatively an increase in leafy green vegetables failed to lower homocysteine.[2]

Energy Levels

The metabolism of every cell in the body depends on vitamin B12, as it plays a part in the synthesis of fatty acids, nutrients and energy production.

Vitamin B12 enables the release of this energy by helping the body to metabolise nutrients and stimulates the body's utilisation of proteins, fats and carbohydrates. For this reason, Vitamin B12 is referred to as the energy vitamin, as it often increases energy levels, whether obtained from eating B12 foods or from supplemental use.[4]

Red Blood Cell Production

Vitamin B12 is required for all rapidly dividing cells. It is involved in the production of red blood cells in bone marrow, and activates folacin coenzymes for red blood cell production.[1] A deficiency of the vitamin results in enlargement of red blood cells that are immature and inefficient at transporting oxygen.[5]

Nervous System Function

Vitamin B12 is required for the synthesis and ongoing health of the myelin sheath and promotes the normal growth of the nervous system.

The myelin sheath surrounds the axons of nerves and serves as insulation, thereby facilitating adequate conduction velocity. Vitamin B12 supports nerve health via its contribution to myelin formation and remyelination. Deficiency of vitamin B12 leads to a defect in myelin synthesis.[3]

As vitamin B12 is vital to the process of myelin formation, B12 is considered essential for the nervous system, particularly in regard to myelin synthesis, nerve metabolism and neuronal regeneration.[6]

References supplied on request.

Designs for Health Quality Guarantee

Designs for Health medicines that are listed on the Australian Register of Therapeutic Goods will display an AUSTL number on the label. Listed medicines in Australia need to be manufactured according to legislated standards set out in Therapeutic Goods Order 101. TGO101 legislation sets out minimum quality standards for medicines supplied in Australia that display an AUSTL number. It mandates testing for:

- Impurities such as heavy metals (including lead, mercury, cadmium and arsenic), pesticides and residual solvents
- Dissolution (to ensure the capsule will dissolve once taken)
- Uniformity (to ensure that every capsule is the same)

Final assay testing is also performed to ensure that what we have on the label is in each capsule, and microbiological testing is performed to ensure that no microbial contamination has occurred during the encapsulation and packing process.