## 🖒 designs for health Australia

# Liposomal Vitamin D3

Supports bone integrity, muscle function and maintains healthy immune system function



### **OVERVIEW**

- New innovative proprietary Liposomal Technology for optimal absorption and delivery
- > Provides support for healthy bones
- > Supports muscle function
- > Maintains healthy immune system function

Active Ingredients per 285 microlitre (1 spray) serve		
Colecalciferol Equiv. Vitamin D3	25 micrograms 1000 IU	
Dack Sizo	50 ml	

Pack Size	50 ml
Servings Per Pack	175

#### Excipients

Purified water	
Lecithin (sunflower)	
Equiv phospholipids	40.7 mg/g
Orange oil (flavour)	
Tocofersolan	
Glycerol	
Ethanol	

#### **Directions for Use**

Adults: Take 285 microlitres (1 spray) daily by mouth, or as directed by your healthcare professional. Spray directly onto the inner cheek or under the tongue and hold in mouth for 30 seconds before swallowing.

#### Allergen Information

No added: Soy, gluten, dairy, lactose or nuts

#### Warnings

Contains ethanol 12%. Vitamin supplements should not replace a balanced diet.

#### Storage Instructions

Store below  $8^\circ\text{C}$  (refrigerate) and keep away from direct sunlight.

Designed and packed in Australia from imported ingredients.







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#### **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 fig.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.<sup>6</sup>

#### 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.<sup>8</sup>

One way to monitor the integrity of the spheres to ensure medicine retention is to measure the net charge or "zeta potential".<sup>8</sup>

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.<sup>9</sup>



#### Zeta potential measurement<sup>9</sup>

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.





## Liposomal Vitamin 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<sup>7</sup>

- 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

#### VITAMIN D - AN OVERVIEW

Vitamin D is a fat-soluble secosteroid hormone that can be found in three main forms – vitamin D (calcitriol), vitamin D2 (ergocalciferol), and vitamin D3 (colecalciferol). Calcitriol is endogenously produced in the body via ultraviolet B exposure to the epidermis.<sup>1</sup> Ergocalciferol is the synthetic form of vitamin D and is most commonly added to food. Colecalciferol is synthesised in the skin from 7-dehydrocholesterol and is also found in a limited range of food sources such as shiitake mushrooms and oily fish. Vitamin D is required for a vast number of biological processes.<sup>1</sup>

Due to a number of disease states having low vitamin D status in common, serum vitamin D as 25-hydroxyvitamin D (25(OH)D) is often routinely tested. Vitamin D supplementation is suggested in those with a clinical vitamin D deficiency. Variations in vitamin D status are heavily dependent upon a number of factors, including sex, season, location, age, health conditions, and lifestyle.<sup>2</sup>

#### **Bone health**

Vitamin D plays a primary role in maintaining bone health and integrity. Both bone mass and mineralisation require adequate vitamin D levels. Two of the main nutrients involved in strengthening the bone matrix, calcium and phosphorous, require adequate vitamin D in order to maintain homeostasis. Evidence suggests that as we age, vitamin D levels can decrease, leading to an imbalance in calcium and phoshorous.<sup>3</sup> Hormonal factors also influence bone resorption and formation – therefore, vitamin D is both directly and indirectly responsible for processes involved in the mineralisation of the extracellular matrix in bone tissue.<sup>4</sup>

#### Immune system

The immune system requires optimal vitamin D levels to function. A number of important immune cells have vitamin D receptors and vitamin D metabolising enzymes, including monocytes, B cells, T cells, and antigen-presenting cells.<sup>5</sup>

Results from *in vivo* human and animal studies show numerous beneficial outcomes for immune function with vitamin D supplementation.<sup>5</sup> Calcitriol has specifically been shown to support macrophage and monocyte antimicrobial activity, as well as maintaining innate immune cell chemotaxis and phagocytosis.<sup>5</sup> Calcitriol is also involved in adaptive immunity where it directly influences B cell homeostasis, memory and plasma cell inhibition, and promotion of apoptosis of immunoglobulins responsible for producing B cells.<sup>5</sup>

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.