

**ENPREVIT® VITAMIN.**

**(VITAMIN A, VITAMIN B-COMPLEX AND GINSENG TABLETS)**

**SUBMITTED BY: NALIS PHARMACEUTICALS LTD**

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**SUMMARY OF PRODUCT CHARACTERISTICS**

**(SmPC) .**

## 1. NAME OF THE DRUG PRODUCT

Enprevit® Vitamin Tablet

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Vitamin A Acetate B.P.....	2000 IU
Vitamin B <sub>5</sub> B.P.....	200 IU
Vitamin B <sub>1</sub> (Thiamine HCl) B.P.....	1mg
Vitamin B <sub>2</sub> (Riboflavin) B.P.....	1mg
Vitamin B <sub>6</sub> (Pyridoxine) B.P.....	5mg
Niacinamide BP.....	15mg
Ginseng.....	990mcg
Excipients.....	q.s

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamins A and B-complex deficiencies. Enprevit is also indicated for healthy body, growth, good appetite, convalescence, and all conditions where there is need to withstand stress and increased demands.

### 4.2 Posology and method of administration

Prophylactic

Adults and children over 12 years

One tablet daily

Or as prescribed by a physician

### 4.3 Contraindications

Known sensitivity to any of the ingredients.

### 4.4 Special warnings and precautions for use

No special warnings.

### 4.5 Interaction with other drug products and other forms of interaction

The pyridoxine hydrochloride may reduce the effectiveness of levodopa.

### 4.6 Fertility, pregnancy and lactation

Considered safe in the recommended dose.

### 4.7 Effects on ability to drive and use machines

None stated

### 4.8 Undesirable effects

None known

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the regulatory bodies such as NAFDAC.

### 4.9 Overdose

Not applicable

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

#### Vitamin A Acetate

Vitamin A is required for growth and bone development, vision, reproduction and the integrity of mucosal and epithelial surfaces. In the retina, retinol is converted to the aldehyde, cis-retinal, which combines with opsin to form rhodopsin, the visual pigment.

#### Vitamin B Complex.

Niacin (Vit B<sub>3</sub>): Niacin can decrease lipids and apolipoprotein B (apo B)-containing lipoproteins by modulating triglyceride synthesis in the liver, which degrades apo B, or by modulating lipolysis in adipose tissue. Niacin inhibits hepatocyte diacylglycerol acyltransferase-2.

Thiamine Hydrochloride (Vit B<sub>1</sub>): A water soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

Riboflavin Sodium Phosphate (Vit B<sub>2</sub>): A water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolic processes.

Niacinamide: A water soluble vitamin considered part of the Vitamin B group. Converted to Nicotinamide Adenine Dinucleotide and Nicotinamide Adenine Dinucleotide Phosphate in the body, both of which are co-enzymes important in electron transfer in respiratory reactions.

Pyridoxine Hydrochloride (Vit B<sub>6</sub>): A water soluble vitamin. Involved in carbohydrate and fat metabolism, but also important in haemoglobin formation.

Ginseng

It is commonly believed that most pharmacological effects of *P. ginseng* are attributed to ginsenosides, including the stimulatory and inhibitory effects on the nervous system, antineoplastic effects, immunomodulatory effects, and nitric oxide release.

## 5.2 Pharmacokinetic properties

The B-complex vitamins are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

Newly absorbed vitamin A is stored in the liver as retinyl esters. Storage involves both the hepatic parenchymal cells and the nonparenchymal stellate cells. Vitamin A is mobilized from liver stores and transported in plasma as retinol bound to a specific transport protein, retinol-binding protein.

After oral ingestion, ginsenoside metabolites are absorbed from the gut into systemic circulation.

## 5.3 Preclinical safety data

None stated

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Methyl paraben, propyl paraben, corn starch, lactose

BP: British Pharmacopoeia

## 6.2 Incompatibilities

None known

## 6.3 Shelf life

24 months

## 6.4 Special precautions for storage

Store between 4°C and 25°C. Protect from light.

## 6.5 Nature and contents of container

PVC blisters and aluminium foil.

## 6.6 Special precautions for disposal of used medicinal product or waste materials derived from such medicinal product and other handling of the product

None stated

## 7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

NAME:  
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## 8. DRUG PRODUCT MANUFACTURER

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## 9. NAFDAC REGISTRATION NUMBER(S):

A11-100476