# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Vikonon Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | |
|---|---|
| Calcium Glycerophosphate BP | 130mg |
| Calciferol BP | 240iu |
| Thiamine Hydrochloride BP | 3mg |
| Alpha Tocopheryl Hydrogen Succinate BP | 10mg |

## 3 PHARMACEUTICAL FORM

Sugar Coated Tablet

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Vitamin Supplement

### 4.2 Posology and method of administration

Adults and Elderly: One tablet per day, by mouth

Children: Not recommended

## 4.3 Contraindications

- Oral administration in the treatment of deficiency state in malabsorption syndromes.
- Hypersensitivity to any of the ingredients.
- History of hypervitaminosis D.
- Hypercalcaemia.
- Metastatic Calcification.
- Abnormal metabolic sensitivity to Vitamin D.

## 4.4 Special warnings and precautions for use

Warning: Do not exceed the stated dose.

Prolonged use should only be on the advice of a physician.

If you suffer from an urinary or kidney disorder then seek medical advice before taking this product.

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

- Bile acid resins such as cholestyramine and colestipol impair the absorption of fats including Vitamin B.
- As both Vitamin D and thiazide diuretics increase the plasma concentration of calcium, co-administration may result in hypercalcaemia.
- The hypercalcaemia which may result from the administration of Vitamin D enhances the toxic effects of cardiac glycosides. Vitamin D also enhances magnesium absorption.
- Liquid paraffin, used as a laxative, and other agents affecting the motility of the GI tract may interfere with the absorption of the fat soluble vitamins.

## 4.6 Fertility, pregnancy and lactation

In humans, idiopathic hypercalcaemia is associated with supravalvular aortic stenosis and this lesion has also been reported when large doses of vitamin D are given to pregnant rabbits. Vitamin D may induce maternal neonatal hypocalcaemic tetany. In nursing mothers, maternal hypercalcaemia may result in neonatal hypercalcaemia as calcium and Vitamin D are excreted in breast milk.

Doses of Vitamin D in excess of those recommended should be avoided during pregnancy and lactation.

## 4.7 Effects on ability to drive and use machines

None

## 4.8 Undesirable effects

Vitamin D can lead to overt toxicity. Calcium metabolism is disturbed and calcification of soft tissue including the lungs and kidneys results. Cerebral and cardiovascular damage is also observed and infants appear particularly vulnerable. In infants showing increased sensitivity to the vitamin hypercalcaemia is a serious risk. Adult intakes of more than 50,000 units may lead to poisoning.

Symptoms and signs of hypercalcaemia include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, thirst, polyuria, drowsiness, confusion, nephrocalcinosis, renal calculi and in severe cases, cardial arrhythmias, coma and cardiac arrest.

The above effects are generally only likely to occur if doses in excess of those recommended are taken and/or for prolonged periods.

## 4.9 Overdose

Overdosage is unlikely with Vikonon. Should it occur, symptoms and signs of toxicity are as described under adverse effects. In case of recent ingestion, gastric lavage is recommended while in delayed presentations, mineral oil purgatives may diminish systemic absorption. Treatment is otherwise symptomatic and supportive with attention to cardiac function and fluid and electrolyte balance.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Calcium Glycerophosphate

Oral Calcium supplement. The body contains about 350 - 500 mmol of calcium per Kg body weight.

Calciferol

(Ergocalciferol). An antirachitic agent. Human daily requirements are 100 -

200 units.

Thiamine Hydrochloride

An essential coenzyme for carbohydrate metabolism. Recommended daily intake is 0.7 to 1.0 mg for women to 1.0 to 1.3 mg for men.

Alpha Tocopheryl Hydrogen Succinate

Acts as an antioxidant for certain fats and is involved in metabolic reactions.

Deficiency is associated with neurological syndromes.

## 5.2 Pharmacokinetic properties

*Calcium Glycerophosphate*

Soluble in aqueous media. The amount absorbed will depend upon the requirements of the body. Excretion is mainly in the urine with smaller amounts lost in the faeces and though sweating.

*Calciferol*

Well absorbed from the GI tract. Hydoxylated in the liver, and then further hydroxylated and metabolised in the kidneys. Excreted mainly in the bile and faeces with only small amounts excreted into the urine. Certain vitamin D substances may be excreted into breast milk.

*Thiamine Hydrochloride*

Absorbed from the GI tract and is widely distributed in most body tissues. It is not stored in the body and excess amounts are excreted in the urine.

*Alpha Tocopheryl Hydrogen Succinate*

A fat soluble vitamin. Aborption from the GI tract is dependant on bile. It enters the blood via the lymphatic system. It is partially metabolised in the liver and excreted in the urine and (mainly) bile.

### 5.3 Preclinical safety data

None stated

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose, Magnesium Stearate, Stearic Acid, Aerosil, Starch, Coating, E122, E127, E171, Syrup, Ethyl Cellulose, Sucrose, Talc, Kaolin, E171 Titanium Dioxide, Acacia.

### 6.2 Incompatibilities

None known other than shown under interactions (4.5).

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

Store between 4°C and 25°C

### 6.5 Nature and contents of container

Strip packs of 10 tablets

### 6.6 Special precautions for disposal

None stated

## 7 MARKETING AUTHORISATION HOLDER

Neo Laboratories Ltd.
51-53 Stert Street
Abingdon
Oxfordshire OX14 3JF
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 2019/5000R

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 March 1989 / 25 January 1995

## 10 DATE OF REVISION OF THE TEXT

15/04/2009