1. NAME OF THE MEDICINAL PRODUCT

{(ZINCOVIT) Vitamins, Essential Minerals & Zinc Tablets}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sugar-coated tablet

contains:

VITAMINS

Vitamin A (as acetate) BP	5000IU
Vitamin B3 (Colecalciferol) BP	400IU
Vitamin E (as di α-Tocopheryl acetate BP	15mg
Thiamine nitrate BP	10mg
Riboflavin BP	10mg
Pyridoxine hydrochloride BP	2mg
Cyanocobalamin BP	7.5mcg
Nicotinamide BP	50mg
Calcium pantothenate BP	10mg
Ascorbic acid BP	75mg

MINERALS

Magnesium oxide BP	30mg
Manganese sulphate BP	2.8mg
Copper sulphate pentahydrate BP	2mg
Zinc sulphate pentahydrate BP	63mg
Selenium dioxide BP	70mcg

3. PHARMACEUTICAL FORM

A single tablet in two (2) Alu-Alu strips of 15 tablets each in a secondary carton with leaflet.

4. Clinical particulars

4.1 Therapeutic indications

{Zincovit tablets} is recommended as:

- Therapeutic supplements during growth, pregnancy, and surgery.
- For conditions due to vitamin and zinc deficiency states like phrynoderma, acrodermatitis enteropathica, folliculitis
- As an adjuvant to antibiotic therapy

4.2 Posology and method of administration

Posology

The dose range is one tablet daily for adults.

Method of administration
Oral

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Zincovit should be used as a vitamin and mineral source in conjunction with an energy-providing diet suitable for individual patient requirements. No other vitamins, minerals, or supplements with or without vitamin A should be taken with this preparation except under medical supervision. Do not exceed the stated dose. Zincovit should be used with caution in patients with chronic liver disease and in patients with hyperlipidemia. Vitamin D should be used with caution in patients with hypercalcemia. Increased sensitivity to Vitamin D is observed in patients with renal impairment and having an abnormal calcium/phosphorus ratio.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of vitamin D may be reduced in patients taking barbiturates or anti-convulsant due to accelerated metabolism of vitamin D. Zinc sulfate reduces the absorption of tetracyclines.

4.6 Pregnancy and Lactation

Women who are or might become pregnant should avoid taking daily supplements containing more than 5000IU Vitamin A, without consulting a medical practitioner. Caution should be used in pregnancy as excessive doses of Vitamin A may be teratogenic, especially when taken in the first trimester. Large doses of vitamin D may cause hypercalcaemia in infants.

4.7 Effects on ability to drive and use machines.

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Zincovit is well tolerated in recommended doses. Some patients may experience mild central stimulant side effects.

4.9 Overdose

Symptoms of overdose may include anorexia, nausea, vomiting, rough dry skin, polyuria, thirst, loss of hair, painful bones, and joints as well as raised plasma and urine calcium and phosphate concentration.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Nutritional supplement

ATC code: A11

Zincovit plays an essential role in the growth and development of bones as well as teeth of the foetus. The vitamins, minerals and trace elements present in this composition may correct and prevent the impairment of the cell metabolism in situations with increased demands and its active form cholecalciferol can pass through placenta and help I calcium metabolism of foetus. Zincovit participates in the synthesis of DNA and RNA, playing a significant role in reproduction. Deficiency of Vitamins A, E, B6 and C also all vitamins and minerals to correct these deficiency states.

5.2 Pharmacokinetic properties

Zincovit is well absorbed from the gastrointestinal tract after oral doses, and it is widely distributed in the body tissues. It enters the systemic circulation and then metabolism takes place in the liver. Finally, the various metabolites are excreted in urine and faeces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container <and special equipment for use, administration, or implantation>

A single tablet in two (2) Alu-Alu strips of 15 tablets each in a secondary carton with leaflet.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

Manufactured by:
APEX Laboratories Private Limited
B-23, SIDCO Pharmaceutical Complex, Alathur-603110, Tamil Nadu, India.

Marketed and Distributed by:
Phillips Pharmaceuticals (Nigeria) Limited
122-132 Afprint Industrial Estate, Iyana-Isolo, Lagos, Nigeria.