SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Concavit Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Capsule contains: -

Vitamin A BP	5000.00 iu
Calciferol BP	500.00 iu
Ascorbic Acid BP	40.00 mg
Thiamine Mononitrate BP	2.50 mg
Riboflavine BP	2.50 mg
Pyridoxine Hydrochloride BP	1.00 mg
Nicotinamide BP	20.00 mg
Calcium Pantothenate BP	5.00 mg
dl-α -Tocopheryl Acetate BP	2.00 iu

3. PHARMACEUTICAL FORM

Soft Gelatine Capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a supplement of multiple vitamins in situations of special dietary need. Not suitable for the correction of specific vitamin deficiencies.

4.2 Posology and method of administration

Adults, The Elderly and Children - 1 capsule daily

4.3 Contraindications

- Oral administration in the treatment of deficiency state in malabsorption syndromes.
- Hypersensitivity to any of the ingredients.
- History of hypervitaminoses A or D.
- Sarcoidosis
- Hypercalcaemia
- Abnormal metabolic sensitivity to Vitamin D.
- Do not take Vitamin A supplements if you are pregnant or likely to become pregnant except on the advice of a doctor or antenatal clinic.

4.4 Special warnings and precautions for use

There are serious risks of developing hypercalcaemia when calcium salts or thiazides are co-administered. Serum calcium, phosphate, alkaline phosphatase, liver function tests and magnesium should be monitored when indicated.

Absorption of Vitamin A is reduced in cystic fibrosis, hepatic diseases, pancreatic dysfunction and in patients with intestinal infections. The use of Vitamin A in renal diseases requires extreme caution.

4.5 Interactions with other medicinal products and other forms of interaction

- Contraceptive pills raise plasma levels of Vitamin A.
- Agents such as bile acid resins, e.g. cholestyramine and colestipol impair the absorption
  of fats including the Vitamins A and D.
- As both Vitamin D and thiazide diuretics increase the plasma concentration of calcium,
  co-administration of these agents may result in hypercalcaemia.
- Hypercalcaemia, which may result from administration of Vitamin D enhances the toxic
  effects of cardiac glycosides. Vitamin D also enhances magnesium absorption.
- The effects of Vitamin D on the intestinal absorption of calcium and bone resorption
  may be reduced by concomitant administration of barbiturates or anticonvulsants.
- Liquid paraffin, used as a laxative, and other agents affecting motility of the
  gastrointestinal tract may interfere with the absorption of fat soluble vitamins.
- Pyridoxine antagonises the effects of L-Dopa unless a dopa-decarboxylase inhibitor is given concurrently.

4.6 Pregnancy and lactation

Animal reproduction studies in several species have shown that when maternal intake is excessive, Vitamin A has been associated with major foetal abnormalities. Vitamin A is found in breast milk of lactating mothers and there is therefore a theoretical risk of neonatal toxicity.

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 A and 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 A
Vitamin A toxicity, initially presenting with irritability, vomiting, loss of appetite and skin changes, has been reported especially in children. In chronic hypervitaminosis, increased intracranial pressure and cirrhosis like liver syndrome are observed. Resolution of the symptoms usually occurs upon withdrawal of the vitamin. A daily dose in excess of 150,000 iu or a single intake of more than 1,500,000 iu often leads to toxicity.

Vitamin D
Vitamin D can also 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

Should overdose occur, symptoms and signs of toxicity are as described under undesirable effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vitamin A, fat soluble vitamin important in growth, development and maintenance of epithelial tissue and for vision.
Calciferol, fat soluble vitamin important in calcium and phosphate homeostasis and in bone mineralisation.
Ascorbic Acid, water soluble vitamin important in synthesis of collagen and intercellular material.
Thiamine, water soluble vitamin important in carbohydrate metabolism.
Riboflavine, water soluble vitamin important in catabolism.
Pyridoxine, water soluble vitamin mainly important in amino acid metabolism but also plays a part in carbohydrate and fat metabolism.
Nicotinamide, water soluble, converted to NAD and NADP in which form plays an important part in electron transfer in respiratory biochemistry.
Calcium Pantothenate, which forms part of coenzyme A.
dl α-Tocopheryl Acetate, fat soluble vitamin which acts as an antioxidant preventing oxidation of polyunsaturated fatty acids.

5.2 Pharmacokinetic properties

The fat soluble vitamins A and D (calciferol) are well absorbed from the GI tract. They are stored in the liver (vitamin A) or in adipose and muscle tissue (calciferol). They are bound to specific α-globulins when in the blood.

Tocopheryl Acetate is absorbed from the GI tract following solubilisation by bile and is dependent on normal pancreatic function. It is absorbed via the lymphatic system. It is partially metabolised in the liver but most is slowly excreted in the bile.

The water soluble vitamins are well absorbed from the GI tract. They tend not to be stored in the body and are excreted unchanged or partially oxidised in the urine.

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya bean oil
Fat mix
Soya Lecithin
Gelatin
Glycerin
Sorbitol
Ethyl para-hydroxybenzoate
Propyl para-hydroxybenzoate
Ponceau 4R
Water

6.2 Incompatibilities

See interactions (4.5)

6.3 Shelf life

36 months

6.4 Special precautions for storage

Keep in a cool place

6.5 Nature and contents of container

25 capsules in white flint Glass vial with polythene closure
100 capsules in amber round glass jar with polycap closure

6.6 Instructions for use and handling

Keep out of the reach of children.

7 MARKETING AUTHORISATION HOLDER

Wallace Manufacturing Chemists Ltd.
Wallace House
51-53 Stert Street
Abingdon
Oxfordshire OX14 3JF
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00400/5009R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st May 1972, 3rd August 1994

10 DATE OF REVISION OF THE TEXT

17/04/2009