SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Concavit Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains: -

Vitamin A BP	5000.00 in
Calciferol BP	500.00 iu
Ascorbic Acid BP	19.35 mg
Sodium Ascorbate USP	34.44 mg
Thiamine Hydrochloride BP	2.00 mg
Ribofiavine	1.00mg
(as Ribofiavine Sodium Phosphate BP)	(1.37 mg)
Pyridoxine Hydrochloride BP	1.00 mg
Nicotinamide BP	12.50 mg
d-Panthenol	2.00 mg

3. PHARMACEUTICAL FORM

Oral Liquid.

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

Oral administration

Adults, and children -5 ml per day.
Elderly – No specific dose recommendation

4.3 Contra-Indications

- 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 Special 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.

Do not exceed stated dose.

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 stated.

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

See Undisirable Effects.

Overdosage is unlikely with Concavit products. Should it occur, symptoms and signs of toxicity are as described under undesirable 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 hepatic and cardiac function and fluid and electrolyte balance.

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, Ascorbate, water soluble vitamin important synthesis of collagen and intracellular material.

Thiamine, water soluble vitamin important in carbohydrate metabolism.

Riboflavine, water soluble vitamin mainly important in amino acid metabolism but also plays a part in carbohydrate and fat metabolism.

Pyridoxine, water soluble vitamin mainly important in amino acid metabolism but also plays a in carbohydrate and fat metabolism.

Nicotinamide, water soluble, converted to NAD and NADP in which form plays a part in electron transger in respiratory biochemistry.

Panthanol, alcoholic anolgue of panthothnic acid which forms part of co-enzyme A.

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 X-globulins when in the blood.
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.

All actives are in solution and bioavailable.

5.3 Pre-clinical Safety Data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium Edetate, Glycerin, Polysorbate 80, Propylene Glycol, Hydroxybenzoates (Methyl, Ethyl, Propyl & Butyl), Progallin P, Flavouring (Essence Soluble Orange Oil & Essence Morella Cherry), Sodium Saccharin, Sorbitol Solution and Water

6.2 Incompatibilities

See section 4.5 (Interactions with other Medicinal Products and other Forms of Interactions).

6.3 Shelf Life

36 Months.

6.4 Special Precautions for Storage

Store in a cool place. Protect from light.

6.5 Nature and Contents of Container

Glass bottle containing 150ml of Concavit Syrup.

6.6 Instructions for Use, Handling and Disposal

None Stated.

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 00400/5012R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 May 1972 / 21 April 1994.

10 DATE OF REVISION OF THE TEXT

17/04/2009