SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calcimax Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:-

Calcium Levulinate	350.00 mg
Calcium Chloride Dihydrate BP	120.00 mg
Nicotinamide BP	2.00 mg
Riboflavine BP	0.125 mg
Thiamine HCl BP	0.50 mg
Pyridoxine HCl BP	0.125 mg
Ascorbic Acid BP	5.00 mg
Calcium Pantothenate BP	0.125 mg

3. PHARMACEUTICAL FORM

Oral Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a dietary supplement of Calcium and Vitamins B & C in situations of special dietary need.
Not suitable for correction of deficiency states.

4.2 Posology and method of administration

Adults and Elderly: Four 5ml spoonfuls twice or more times per day as directed by a doctor. Children: One to Two 5ml spoonfuls three times per day according to age or as directed by a doctor.

4.3 Contra-indications

Hypercalcaemia and severe hypercalciuria, Vitamin D overdose, decalcifying tumours, severe renal failure, renal calculi.

4.4 Special warnings and special precautions for use

Use with caution in patients with renal impairment. The syrup contains sucrose and this may adversely affect dental hygiene or control of diabetes. Calcimax has propylene glycol as a preservative and hypersensitivity reactions may occur in susceptible individuals.

4.5 Interactions with other medicinal products and other forms of interaction

High vitamin D intake should be avoided during calcium therapy unless specially indicated. Although it is unlikely that hypercalcaemia will result from the administration of Calcimax, there is a risk of adverse digoxin effects in digitalised patients.
Oral Calcium may reduce the absorption of Tetracyclines.
Pyridoxine may antagonise effects of L-dopa unless the patient is receiving a peripheral Dopa-decarboxylase inhibitor.
Co-administration of thiazides increases the risk of hypercalcaemia.

4.6 Pregnancy and lactation

Epidemiological studies have shown no increase in the teratogenic hazard to the foetus if used in the dose recommended for usual vitamin and calcium supplementation. Although calcium and other vitamins are excreted in breast milk, the concentration is not sufficient to produce an adverse effect on the neonate when taken in recommended doses.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Mild gastrointestinal disturbances may occur. Although hypercalcaemia would not be expected in patients unless renal function is very impaired, occurrence of nausea, vomiting, anorexia, constipation, abdominal pain, thirst, polyuria and muscle weakness should alert to the possibility of hypercalcaemia.

4.9 Overdose

The amount of calcium absorbed following overdosage will depend on the individual's calcium status. It might cause hypercalcaemia especially in patients treated with excessive doses of Vitamin D.
Treatment is supportive and symptomatic and is aimed at lowering serum calcium levels, eg by administration of oral phosphates. Monitoring of cardiac, renal and fluid status is advisable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium Salts - Treatment of calcium deficiency. Vitamin C & B complex - Vitamin supplement.

5.2 Pharmacokinetic properties

All actives are in solution and bioavailable.

5.3 Preclinical safety data

Not Applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Edetate, Sucrose, Glycine, Sodium Saccharin, Nipasept, Nipabutyl, Propylene Glycol, Glycerin, Soluble Orange Oil, Essence Morella Cherry, Burnt Sugar, Hydrochloric Acid, Deionized Water.

6.2 Incompatibilities

See under interactions.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30 ºC

6.5 Nature and contents of container

150ml Amber Glass Bottle.

6.6 Instructions for use, handling and disposal

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(S)

PL 00400/5007R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE

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14 October 1988 / 14 October 1993

10 DATE OF REVISION OF THE TEXT

17/04/09