Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gevral Instant Protein Orange Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active constituents

Vitamin A Palmitate	1250	IU
Vitamin D_3	125	IU
VitaminB_1 (as thiamine mononitrate)	1.1	mg
Vitamin B_2 (Riboflavin)	1.1	mg
Vitamin B_6 (Pyridoxine HCl)	0.1	mg
Vitamin B_{12} (as cobalamin concentrate-the extract from streptomyces fermentation)	0.5	micrograms
Vitamin C (Ascorbic Acid)	12.5	mg
Vitamin E (*dl*-Alpha tocopherol acetate)	2.25	IU
Pantothenic acid (as Calcium pantothenate)	1.8	mg
Niacin	5.25	mg
Calcium (as dibasic calcium phosphate and from soya protein isolate and non fat milk powder)	150	mg
Phosphorus (as dibasic calcium phosphate and from soya protein isolate and non fat milk powder)	160	mg
Elemental Iron (as ferrous fumarate and from soya protein isolate and non-fat milk powder)	3.0	mg
Lysine (from soya protein isolate and non-fat milk powder)	450	mg
Choline (from choline, non-fat milk powder and soya protein isolate)	13	mg
Inositol (from inositol, non-fat milk powder and soya protein isolate)	37.5	mg
Copper (as copper oxide)	0.3	mg
Iodine (as potassium iodide)	37.5	micrograms
Potassium (from potassium sulphate and soya protein isolate) Not less than	45	mg
Manganese (as manganese dioxide and from non-fat milk powder and soya protein isolate)	0.35	mg
Zinc (as zinc oxide)	0.4	mg
Magnesium (as magnesium oxide and from non-fat milk powder)	5.5	mg

For excipients see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral suspension.

A fine cream coloured powder with an orange flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of appropriate vitamin and mineral deficiencies.

4.2 Posology and method of adminstration

Oral. 1 x 15g sachet daily

4.3 Contraindications

Use in patients with a known hypersensitivity to any of the active constituents.

4.4 Special warnings and precautions for use

While children are taking this product, no other vitamin supplement containing vitamin A and D should be taken, unless under medical supervision.

Prolonged excessive ingestion of vitamin A and D can lead to hypervitaminosis states which may occur if foods high in this vitamin, (for example liver), are ingested in association with the recommended doses of this product.

4.5 Interaction with other medicinal products and other forms of interaction

- The content of pyridoxine may interfere with the effects of concurrent levodopa therapy.
- Care should be taken in the concomitant use of this preparation with tetracyclines as iron salts diminish the absorption of tetracyclines.

4.6 Pregnancy and lactation

This product should not be taken during pregnancy or lactation unless considered essential by the physician.

Large doses of vitamin A have been found to be teratogenic if administered during the first trimester of pregnancy.

Vitamin D given during the last trimester of pregnancy may cause hypercalcaemia in infants.

It is advised that if possible women receiving vitamin D do not breastfeed their infants as this may lead to the development of hypercalcaemia in the infant.

4.7 Effects on ability to drive and use machines

None Stated.

4.8 Undesirable effects

Mild gastrointestinal side effects.

4.9 Overdose

None Stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vitamins play an essential part in normal body functions. They help with the production of energy from food and the regulation of the metabolism. Each metabolic process involves a specific enzyme and usually a particular vitamin or mineral to aid the biochemical reaction. Vitamins are a normal and essential part of the diet which the body extracts from food during digestion.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Embanox 3 (mixture of butylhydroxyanisolum, propyl gallate and citric acid)
Vanillin
Soya protein isolate
Non-fat milk powder
Icing sugar with TCP (mixture of sucrose and tricalcium phosphate)

Variable constituents according to flavour

Orange Flavour

Orange flavour No. 6004
Sunset yellow (E110)

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Carton with foil laminate sachets, consisting of aluminium foil, paper, polyethylene and thermosealing resin.

Each sachet contains 15g of powder. 14 sachets per carton

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Whitehall Laboratories Ltd.,
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Huntercombe Lane South
Taplow
Maidenhead
Berkshire, SL6 0PH
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8 MARKETING AUTHORISATION NUMBER

P.A. 172/31/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

March 2004