Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gevral Instant Protein Chocolate Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Vitamin A Palmitate (as Synthetic Retinol Conc. Ph.Eur.)	1250	IU
Vitamin D_3 (as Colecalciferol Ph. Eur.)	125	IU
Vitamin B_1 (as Thiamine Mononitrate)	1.1	mg
Vitamin B_2 (as Riboflavin Ph. Eur.)	1.1	mg
Vitamin B_6 (as Pyridoxine Hydrochloride Ph. Eur.)	0.1	mg
Vitamin B_{12} (as Cobalamin concentrate - the extract from streptomyces fermentation)	0.5	micrograms
Vitamin C (Ascorbic Acid Ph. Eur.)	12.5	mg
Vitamin E (*dl*-Alpha Tocopherol Acetate Ph. Eur.)	2.25	IU
Pantothenic acid (as calcium pantothenate)	1.8	mg
Niacin (as niacinamide and from non-fat milk powder and soya protein isolate)	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 and cocoa powder)	3.0	mg
Lysine (from non-fat milk powder and soya protein isolate)	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 and from non-fat milk powder, soya protein isolate and cocoa powder)	0.3	mg
Iodine (as potassium iodide)	37.5	mg
Potassium (from potassium sulphate, soya protein isolate, non-fat milk and cocoa powder) not less than	75	mg
Manganese (as manganese dioxide and from non-fat milk powder and soya protein isolate)	0.35	mg
Zinc (as zinc oxide and from non-fat milk powder and soya protein isolate and cocoa powder)	0.4	mg
Magnesium (as magnesium oxide and from non-fat milk powder, soya protein isolate, non-fat milk and cocoa powder)	12.0	mg

For excipients , see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral suspension.

A fine light brown powder with a chocolate 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

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

Variable constituents according to flavour

Chocolate flavour

Cocoa powder

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.,
Trading as: Wyeth Consumer Healthcare
Huntercombe Lane South
Taplow
Maidenhead
Berkshire, SL6 0PH
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8 MARKETING AUTHORISATION NUMBER

PA 172/31/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

March 2004