Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pharmaton Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

(G115) Panax Ginseng extract [dry extract ethanolic 40%:1.3-3:1]	40.0	mg
Vitamin A concentrate (oily form) synthetic (for Vitamin A)	2667.0	IU
Cholecalciferol concentrate (oily form) [Vitamin D3]	200.0	IU
all-rac- µ-tocopheryl acetate [Vitamin E]	10.0	mg
L-Ascorbic acid [Vitamin C]	60.0	mg
Thiamine nitrate [Vitamin B1 mononitrate]	1.4	mg
Riboflavin [Vitamin B2]	1.6	mg
Nicotinamide	18.0	mg
Pyridoxine hydrochloride [Vitamin B6]	2.0	mg
Folic acid	100.0	micrograms
Cyanocobalamim [Vitamin B12]	1.0	micrograms
Biotin	150.0	micrograms
Calcium (as anhydrous dibasic calcium phosphate)	100.0	mg
Iron (as dried ferrous sulphate)	10.0	mg
Magnesium (as dried magnesium sulphate)	10.0	mg
Zinc (as zinc sulphate monohydrate)	1.0	mg
Copper (as dried copper sulphate)	2.0	mg
Selenium (as dried sodium selenite)	50.0	micrograms
Lecithin (containing choline, inositol, linoleic acid, linolenic acid)	100.0	mg

Excipients: Each capsule contains arachis oil (1.32 mg) and lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules, soft (short term: capsule)
Dark brown, opaque, oblong, soft gelatin capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of fatigue and weakness associated with stress, convalescence, or the symptoms of ageing, impaired general health.

As a vitamin and mineral supplement for persons requiring dietary adjuncts, as in convalescence, etc. in the correction of specific vitamin deficiencies.

4.2 Posology and method of administration

Adults: The recommended dose is one capsule daily.

The capsule should preferably be taken in the morning with food.

The usual course of treatment with Ginseng lasts 8 to 12 weeks.

Children: Not recommended

4.3 Contraindications

Pharmaton Capsules are contraindicated in patients with disturbances of calcium metabolism (e.g. hypercalcaemia and hypercalciuria), hypervitaminosis A or D, renal insufficiency, concomitant retinoid (e.g. for acne) or vitamin D therapy, haemochromatosis, iron overload syndrome, pregnancy and lactation (see section 4.6) and in patients with known hypersensitivity to any of the ingredients in the product.

Pharmaton Capsules contain arachis oil (peanut oil) and should not be taken by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to soya, patients with soya allergy should also avoid Pharmaton Capsules.

4.4 Special warnings and precautions for use

Patients with a family history of haemochromatosis should seek medical advice before taking Pharmaton Capsules.

Patients receiving any other medication or those under the care of a doctor should consult a physician before taking this product.

Excessive doses of vitamin A or D may lead to hypervitaminoses. An allowance should always be made for intake of these vitamins from other sources.

There is insufficient information on the safety of the product to recommend prolonged use.

If symptoms have not shown any improvement within 4 weeks, patients should consult a doctor.

Patients taking warfarin (or other coumarin anticoagulants) should have increased monitoring of their INR levels when starting or stopping treatment with ginseng containing products.

Each capsule contains a small amount of lactose (26 mg). Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interference with clinical laboratory tests
Biotin may interfere with laboratory tests that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results, depending on the assay. The risk of interference is higher in children and patients with renal impairment and increases with higher doses. When interpreting results of laboratory tests, possible biotin interference has to be taken into consideration, especially if a lack of coherence with the clinical presentation is observed (e.g. thyroid test results mimicking Graves' disease in asymptomatic patients taking biotin or false negative troponin test results in patients with myocardial infarction taking biotin). Alternative tests not susceptible to biotin interference should be used, if available, in cases where interference is suspected. The laboratory personnel should be consulted when ordering laboratory tests in patients taking biotin.

4.5 Interaction with other medicinal products and other forms of interactions

Ginseng may affect the activity of depressants or stimulants which act on the central nervous system.

Ginseng may potentiate the action of antihypertensives.

Interactions of iron with tetracycline antibiotics (tetracycline, doxycycline, minocycline) and vitamin B_6 with levodopa are known. Vitamin B_6 may increase the peripheral metabolism of levodopa thereby reducing the therapeutic efficacy in patients with Parkinson’s disease. Patients on any of these medications should seek medical advice before starting this product.

In case of concomitant intake of ginseng preparations and anticoagulants, the effect of oral blood thinning medication (e.g. warfarin) may potentially be reduced. Patients on blood thinning medications should seek medical advice before starting this product.

4.6 Fertility, pregnancy and lactation

Pregnancy
Pharmaton Capsules are not recommended for use during pregnancy and lactation (see section 4.3). There is no report of experience in human pregnancy.

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.

WARNING: Do not take Vitamin A supplements if you are pregnant or likely to become pregnant except on the advice of a doctor or ante-natal clinic.

Fertility
No studies on the effect on human fertility have been conducted with Pharmaton Capsules.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Undesirable effects
Adverse events have been ranked under headings of frequency using the following convention:
Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100);
rare (≥ 1/10000, <1/1000); very rare (<1/10000); not known – cannot be estimated from the available data.

Immune system disorders:
Not known: hypersensitivity, anaphylactic reaction

Psychiatric disorders:
Not known: insomnia

Nervous system disorders:
Common: headache
Not known: dizziness

Gastro-intestinal disorders:
Common: nausea, vomiting
Uncommon: diarrhoea
Not known: abdominal pain

Skin and subcutaneous tissue disorders:
Not known: rash, pruritus

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie;
e-mail: medsafety@hpra.ie.

4.9 Overdose

The toxicity of the product in large overdoses is caused by the toxicity of the liposoluble vitamins A and D. A safe dose for both vitamins is considered to be 5-10 capsules (each capsule contains the EU % RDA for vitamins A and D).

Prolonged supply of larger amounts corresponding to 37 capsules for vitamin A and 10 capsules for vitamin D can cause symptoms of chronic toxicity such as vomiting, headache, drowsiness, and diarrhoea. Acute toxic symptoms are only seen at even higher doses.
Nervousness may occur following an overdose of the product.

The acute toxic dose in adult humans corresponds to about 25,000 to 50,000 IU for vitamin D (contained in 125 to 250 capsules) and about 300,000 to 900,000 IU for vitamin A (contained in 112 to 337 capsules).

The chronic toxic dose in adult humans corresponds to about 2,000 IU for vitamin D (contained in 10 capsules) and about 100,000 IU (contained in 37 capsules) for vitamin A.

Zinc: In general the total daily intake should not exceed 15 mg.

Iron: Severe acute toxicity in man has been reported from doses of iron ranging from 12-1500 x RDA. Most incidents of acute iron toxicity have resulted from accidental oral ingestion of iron pills by children. Longer-term doses of iron up to 6-7 x RDA have been reported to have no toxic effect in some reports (Council for Responsible Nutrition, Safety of Vitamins and Minerals, Washington 1986).

Symptoms: Initial symptoms include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur.

Treatment: To minimise or prevent further absorption of the medication.

- Administration of an emetic

- Gastric lavage with desferrioxamine solution (2 g/l). Then desferrioxamine (5 g in 50-100 ml water) should be introduced into the stomach to be retained.

- Severe poisoning: Shock and/or coma with high iron levels (serum iron >90 micrometrel/l in children, > 142micrometre l/l in adults); immediate supportive measures plus i.v. infusion of desferrioxamine should be instituted.

- Less severe poisoning: i.m. desferrioxamine is recommended (1 g 4-6 hourly in children; 50 mg/kg up to a maximum dose of 4 g in adults).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other combinations of nutrients, ATC code: V06D X

Pharmaton Capsules exert a stimulant effect at physical and psychic levels through the combined action of various substances on the basic metabolic processes.

The standardised ginseng extract G115 raises the general level of cellular activity, which is expressed by a pronounced increase in the physical and mental capacity.

The vitamins and minerals play a role in all basic metabolic processes of the organism. As essential substances, the daily intake of appropriate quantities to supply the daily requirements is very important.

Choline, inositol, linoleic acid and linolenic acid, in the form of lecithin, improve energy output and lipid metabolism.

5.2 Pharmacokinetic properties

Pharmacokinetic studies on Pharmaton Capsules have not been carried out, because of the complex composition of the product and the small quantities of the active ingredients contained. Moreover, these substances are well known.

Pharmacokinetic studies of the standardised ginseng extract G115 are not possible, because it is a complex extract. In the ginseng root more than 100 substances have been identified to date. Pharmacokinetic studies of individual purified ginsenosides, carried out in various animal species, show that already in the stomach numerous metabolites are formed.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule

Rapeseed oil, refined
Hard fat
Ethyl vanillin
Arachis oil, refined (peanut oil)
Triglycerides, medium chain
Gelatin
Lactose monohydrate
Silica, colloidal anhydrous

Capsule shell

Gelatin
Glycerol 85 %
Iron oxide red (E172)
Iron oxide black (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Bottles: 24 months
Blisters: 18 months

6.4 Special precautions for storage

Do not store above 25°C.
Bottle: Keep the bottle tightly closed to protect from moisture.

6.5 Nature and contents of container

Brown glass bottles (hydrolytical class III, Ph. Eur.) with pilfer proof aluminium caps (with rubber inserts) containing either 4, 30, 60, 90 or 100 capsules.

Aluminium blister packs of 4, 30, 60, 90 and 100 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Limited T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/188/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 January 1984

Date of last renewal: 17 January 2009

10 DATE OF REVISION OF THE TEXT

August 2020