# **Summary of Product Characteristics**

#### 1 NAME OF THE MEDICINAL PRODUCT

Pharmaton Capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

(G115) Panax Ginseng extract 40.0 mg (dry extract ethanolic 40%: 1.3-3:1) Vitamin A concentrate (oily form) synthetic (for Vitamin A) 2667.0 IU Colecalciferol concentrate (oily form) (Vitamin D3) 200.0 IU All-rac-α-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 100.0 mg Lecithin

Excipients: Each capsule contains arachis oil and lactose monohydrate

(containing choline, inositol, linoleic acid, linolenic acid)

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Capsules, soft (capsules)

Product imported from the United Kingdom

Dark brown, opaque, oblong soft gelatin capsules.

#### 4 CLINICAL PARTICULARS

As per PA0540/188/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/188/001

#### 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

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

## 6.4 Special precautions for storage

Do not store above 25°C. 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 30 capsules in a cardboard carton.

# 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 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd Unit 625 Kilshane Avenue Northwest Business Park Ballycoolin Dublin 15 Ireland

#### 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/037/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th August 2010

## 10 DATE OF REVISION OF THE TEXT

February 2018