Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ginsana G115 100 mg Soft Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100 mg of standardised dry extract of the dried roots of Panax ginseng C. A. Meyer (1.3 – 3:1). The extract contains 4% w/w of ginsenosides. The extract was manufactured with ethanol (40%).

Each capsule contains 68mg of lactose monohydrate, 44mg of soya oil and 13.5mg of sorbitol.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft
Oblong, brown coloured soft capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the management of patients with impaired general health or those who are convalescent.

4.2 Posology and method of administration

Adults:
The recommended daily dose is 2 capsules taken preferably in the morning with food.
A usual course lasts 8 to 12 weeks.
Not recommended for use in children.
Elderly:
There are no special dosage recommendations for the elderly.

4.3 Contraindications

Ginsana Capsules are contraindicated in patients with known hypersensitivity to any of the ingredients in the product.

Ginsana Capsules contain soya and should not be taken by patients known to be allergic to soya. As there is a possible relationship between allergy to soya and allergy to peanut, patients with peanut allergy should also avoid taking Ginsana Capsules.

In case of intolerance to lactose, an excipient of the product, the use of the product is contraindicated (see section 4.4).

4.4 Special warnings and precautions for use

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

There is some evidence that this product may permit a reduction of insulin dosage and therefore it may require adjustment of control in patients with diabetes mellitus.

Persons receiving any other medications or those under the care of a doctor, should consult the physician before taking this product.

Ginsana Capsules contains a small amount of lactose in each capsule. Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine.

Ginsana Capsules contains a small amount of sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Ginseng may affect the activity of depressant or stimulant drugs acting on the central nervous system. Ginseng may potentiate antihypertensives.

Panax ginseng may reduce the effect of warfarin (or other coumarin anticoagulants).

4.6 Fertility, pregnancy and lactation

Reproduction studies in animals using G115 Panax Ginseng extract showed no adverse effects on fertility, nor any teratogenic effects, but in view of the limitations of these studies the finding must be interpreted with caution. As controlled studies with pregnant women are not available, Ginsana is not recommended for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

In rare cases mild and transient gastrointestinal reactions (such as nausea, stomach pain and diarrhoea) and insomnia have been reported as possibly drug related side effects. In addition, allergic reactions have been rarely reported.

4.9 Overdose

Signs of nervousness may occur following an overdose of the product. General supportive measures should be taken if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ginsana is a preparation containing the standardised *Panax ginseng* extract G115 from the roots of the plant *Panax ginseng* C.A. Meyer.
The pharmacological actions of the standardised *Panax ginseng* extract G115 are considered to be attributed not only to the ginsenosides, but also to the glycans, polysaccharides, and probably to the polyacethylenes and other not yet identified substances contained in the root of the plant *Panax ginseng* C.A. Meyer.
The standardised Panax ginseng extract G115 raises the general level of cellular activity, which is expressed by a pronounced increase in the physical and mental capacity of the patient. In animal experiments, following treatment a reduction of lactic acid concentration in muscles during exercise was seen. An increase of the dopamine and noradrenaline contents and a reduction of the serotonin content in the brain stem could be observed.

5.2 Pharmacokinetic properties

Since the standardised *Panax ginseng* extract G115 is a complex extract containing more than 200 different identified substances, it is very difficult to perform pharmacokinetic studies. Nevertheless, pharmacokinetic studies of individual

purified ginsenosides have been carried out in various animal species.

Using radioactively labelled (^{14}C) Ginsenoside Rg1, originated from the standardised *Panax ginseng* extract G115, a bioavailability of 30% was determined in mice.

With intraperitoneal application, depending on the animal species tested and the type of Ginsenoside, half-lifes of 27 minutes (Ginsenoside Rg1) and 14.5 hours (Ginsenoside Rb1) were measured.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients
Lactose monohydrate (used to standardise the active substance)
Lecithin
Soya lecithin
Rapeseed oil, refined
Wax mixture (yellow beeswax, hydrogenated soya-bean oil and partially hydrogenated vegetable oil)
Ethyl vanillin
Colloidal anhydrous silica (used in the preparation of the active substance)

Capsule Shell
Gelatin
Glycerol
Iron oxide black (E172)
Iron oxide red (E172)
Ethyl vanillin
Anidrisorb (a mixture of sorbitol (E420), mannitol (E421) and sorbitan)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

The capsules are packed in aluminium foil/PVC/PVDC blisters or packed in brown glass bottles, sealed with pilfer-proof aluminium caps. The blisters and the bottles are then further packaged in cardboard cartons.
Pack sizes of 30, 60 and 100. 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

Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 7/62/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 26 June 2009

10 DATE OF REVISION OF THE TEXT

April 2012