

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Ginsana G115 Tonic 140 mg/15 ml Oral Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains 140 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 15 ml contains 2655 mg of sorbitol 70% solution, 1418 mg of ethanol, 1730 mg of sucrose, 210 mg of methylhydroxybenzoate and 210 mg of propylhydroxybenzoate.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral Solution

Brown, clear to slightly turbid, aromatic solution.

## 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 15 ml daily, preferably taken in the morning with food. A usual course lasts 8 to 12 weeks.

Children:

Not recommended.

Elderly:

There are no special dosage recommendations for the elderly.

Ginsana G115 Tonic should be shaken well before use. A slight turbidity is normal with this natural product.

### 4.3 Contraindications

In the absence of experience, the product is not recommended in children.

Hypersensitivity to any of the ingredients.

### 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 medication or those under the care of a doctor should consult the physician before taking this product.

This medicinal products contains 12 vol % ethanol (alcohol). A 15 ml dose is equivalent to 37 ml of 5% beer or to 15 ml of 12% wine per dose. A risk to health exists for people with liver disease, with concomitant use of paracetamol, abusers of alcohol, epileptics, people with brain damage, pregnant and nursing women, as well as for children.

This product contains 1710 mg of sorbitol and 1730 mg of sucrose per 15 ml dose. Diabetics, therefore, should not take Ginsana G115 Capsules which do not contain sugar. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This product contains small quantities of methyl and propyl parahydroxybenzoate. These ingredients may cause allergic reactions (possibly delayed).

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Ginseng may affect the activity of depressant or stimulant drugs which act 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**

Ginsana G115 Tonic contains alcohol and therefore should not be taken during pregnancy or whilst breast-feeding. Controlled studies with pregnant women are so far not available.

#### **4.7 Effects on ability to drive and use machines**

Ginsana G115 Tonic contains alcohol. Drivers and people handling machines should therefore not take this medicine. Ginsana G115 Capsules should be used instead.

#### **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**

No cases of overdosage of this product have been reported to date.

### **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 polyacetylenes 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 content 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 ( $^{14}\text{C}$ ) 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-lives 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

Sucrose (used to standardise the active substance)

Vanilla tincture (contains ethanol)

Quillaia flavour (contains ethanol)

Orange flavour

(contains methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) sucrose)

Sorbitol 70 % solution (non-crystallizing) (E420)

Liqueur wine 16 % v/v (contains ethanol)

Citric acid monohydrate

Sodium citrate dihydrate

Purified water

### 6.2 Incompatibilities

None known.

### 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

Amber Type III bottles containing 250 ml Ginsana G115 Tonic packed into cardboard cartons.

### 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 7/62/2

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

Date of first authorisation: 13 June 1994  
Date of last renewal: 26 June 2009

**10 DATE OF REVISION OF THE TEXT**

April 2012