

S0

CLINICALLY PROVEN

Ginsana

HARD GELATINE CAPSULE

Complementary medicine Category D33.6 (western herbal)
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS **S0**

1. NAME OF MEDICINE

GINCOSAN[®] HARD GELATINE CAPSULE
(100mg Panax ginseng root extract (G115)).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

GINSANA[®] HARD GELATINE CAPSULE: each capsule contains:
Panax Ginseng C.A Meyer (Ginseng).....30-55 mg
[root, as 100 mg of a (1.5-2.75):1 extract G115 standardised to 4% ginsenosides]
Contains sugar: Lactose and mannitol.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard gelatine capsules.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications:

- Enhancement of physical capacities in case of weakness, exhaustion, and tiredness.
- In support of withstanding situations of strain and for strengthening the immune system.
- Shortens the recovery time after periods of increased physical demand.
- Increases the endurance time

4.2. Posology and method of administration

Posology

For individuals between the ages of 12 and 18 years with a body weight <50 kg the recommended daily dosage is: 1 capsule with breakfast.

For individuals between the ages of 12 and 18 years with a body weight ≥50 kg the recommended daily dosage is those for adults.

Adults

Two capsules daily with breakfast, or 1 with breakfast and 1 with lunch. The capsules are best taken with some water.

Elderly: There are no special dosage recommendations for the elderly.

Method of administration

Oral use.

4.3. Contraindications

GINSANA is not recommended for use in children under 12 years.

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

In case of rare hereditary conditions that may be incompatible with an excipient of the product (please refer to section 4.4 "Special warnings and precautions for use"), the use of the product is contraindicated.

4.4. Special warnings and precautions for use

Do not exceed the stated dose. This product contains a maximum amount of 136 mg of Lactose per daily dosage of two capsules.

This product contains 136 mg of lactose per daily dose of two capsules.

Patients with the rare hereditary condition of galactose intolerance, i.e., galactosaemia, should not take this medicine.

4.5. Interaction with other medicines and other forms of interactions

In a study of American ginseng (Panax quinquefolius), another species of ginseng, the extract was shown to reduce the effect of anticoagulants.

Patients on blood thinning medications should seek medical advice before starting GINSANA (please refer to section 4.4 "Special warnings and precautions for use").

4.6. Fertility, pregnancy and lactation

There is limited amount of data from the use of Panax ginseng in pregnant women.

As a precautionary measure, it is preferable to avoid the use of GINSANA during pregnancy

4.7. Effects on ability to drive and use machines

No effects on ability to drive and use machines have been reported.

4.8. Undesirable effects

Gastrointestinal disorders

Nausea, stomach pain, and diarrhoea

Nervous System disorders

Headache

Immune system disorders:

Allergic reactions

Psychiatric disorders

Insomnia

Frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

4.9. Overdose

Clinical effects from overdose in animals and humans have so far not been reported with Panax ginseng extract. However, in such a case, expected side effects can be precipitated and/or be of increased severity (see section 4.8 Undesirable effects).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: ALIMENTARY TRACT AND METABOLISM – TONICS , ATC code: A13A
Mechanism of action

Pharmacodynamic effects

Clinical efficacy and safety

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 as 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 contents in the brain stem could be observed. In a pre-clinical study it was demonstrated that the standardised Panax ginseng extract G115 is able to modulate pro-inflammatory cytokines in mice. An increase of macrophage toll-like receptor 4 during physical stress was in fact observed.

The ability of the standardised Panax ginseng extract G115 to improve energy production and metabolic activity was evaluated in mouse skeletal muscle cell line (in vitro model) and male mice (in vivo model).

The results of the study indicated that treatment with standardised Panax ginseng extract G115 results in increase of AMPK and SIRT1 expression that lead in induction of PGC-1α expression (a gene involved in mitochondrial biogenesis). This translates into an improvement of the energy balance as demonstrated by increased production of ATP and by the increase in oxygen consumption. In addition, the G115 ginseng extract is able to counteract the inhibition of gene expression of AMPK and PGC-1α due to the prolonged strenuous exercise.

These results help to explain the effects of the standardised Panax ginseng extract G115 in improving physical performance.

Clinical pharmacological studies have been performed with the standardised Panax ginseng extract G115 or other ginseng extracts to study the effects on physical performance, mental performance and immune system.

In these studies parameters related to physical performance such as increased maximal oxygen consumption, enhanced haemoglobin oxygen saturation, increased haemoglobin re-oxygenation, increased aerobic phase, increased pulmonary functions were seen.

Other studies showed positive effects on parameters related to immune system such as increased Natural Killer Cells and Antibodies. The influence of parameters related to cerebral activities after G115 extract treatment such as the electroencephalograph the enhanced cerebral flow, and better cognitive functions was reported.

Finally, other studies studied the beneficial effects of ginseng on endothelial and on blood glucose levels.

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 (¹⁴C) 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.

The kinetics of ginsenosides has been determined in humans in four studies.

5.2. Preclinical safety data

The oral LD50 of the standardised Panax ginseng extract G115 is more than 5g/kg of body weight in the mouse and the rat, and more than 2g/kg in the mini-pig.

The effect of the standardised Panax ginseng extract G115 on reproductive performance was studied in two generations of Sprague-Dawley rats. Animals of both sexes were fed either a control diet or a diet supplemented with the standardised Panax ginseng extract G115 at dose levels of 1.5, 5, or 15 mg/kg body weight/day. Parameters of reproduction and lactation in the treated groups were comparable to those of the controls for 2 generations of dams and pups. No treatment-related effects were seen in weekly body weights and food consumption, haematological and blood chemistry parameters, and in ophthalmic, macroscopic, and histopathological examinations.

The standardised Panax ginseng extract G115 administered to pregnant Wistar rats and pregnant New Zealand rabbits caused no abnormality in foetal development. The rats were treated with 40 mg compound/kg/day from the 1st to the 15th day after mating. The rabbits were treated with 20 mg/kg/day from the 7th to the 16th day after mating. The foetuses were removed by caesarean section on the 21st day in the rats and on the 27th day in the rabbits. The product caused no abnormalities in either species.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Silica, colloidal anhydrous; lactose monohydrate; silicon dioxide; mannitol; magnesium stearate; copper complex of chlorophyllins; titanium dioxide; gelatin.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at or below 25 °C.

6.5. Nature and contents of container

The capsules are packed into blisters consisting of transparent (PVC/ PVDC film) on one side and an aluminium foil on the other side. Pack sizes of 30 and 60 hard gelatine capsules. Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

SFI South Africa (Pty) Ltd

121 Mitchell Street

George, 6529

Tel: +27 (44) 874 2927

7. REGISTRATION NUMBER

D552035.

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

9. DATE OF REVISION OF THE TEXT

November 2020.