FLORDIS®
PROFESSIONAL INFORMATION

SFI

CLINICALLY PROVEN

S0

Gincosan®

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) and 60mg Ginkgo biloba leaf extract (GK501)).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

GINCOSAN® 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]
Ginkgo biloba L. (Ginkgo).....60 mg
[leaf, as 60 mg of a 40:1 GK501 extract standardised to 24.5% ginkgoflavon glycosides and 6% terpenes]
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:

- to improve cognitive functions, particularly those related to memory and mental performance, e.g. mental capacity and endurance;
- prevention of mental fatigue;
- improved retention of information;
- reduction of forgetfulness.

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.
Elderly: dosages recommended are the same for adults. For specific background conditions, medical consultation is to be required.

Duration of use

It is recommended to take **GINCOSAN** for at least 4 weeks.

Method of administration

Oral use.
One capsule should be taken after breakfast and the second after lunch.
Capsules should be swallowed whole with some water.

4.3. Contraindications

GINCOSAN 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 366 mg of Mannitol per daily dose of two capsules.
Patients in need to control or limit the consumption of sugars, should be advised by a physician on Gincosan use, to receive adequate directions for each individual situation.
Patients with the rare hereditary condition of galactose intolerance, i.e., galactosaemia, should not take this medicine.
Due to the effects of Ginkgo biloba on blood circulation, caution is advised in patients with bleeding disorders and in those on medications that may increase the risk of bleeding. Medical advice should be sought before planned surgical or dental procedures (please refer to section “Interaction with other medicines and other forms of interactions”).

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.
An interaction may exist between Ginkgo biloba and medications that increase the tendency to bleed (i.e., anticoagulants and antiplatelet drugs).
Patients on blood thinning medications should seek medical advice before starting GINCOSAN. (please refer to section 4.4 “Special warnings and precautions for use”).
The EMA Pharmacovigilance Risk Assessment Committee (PRAC) considers that a pharmacokinetic interaction between efavirenz and Ginkgo biloba extracts is plausible and should be reflected in the product information of efavirenz-containing medicinal products. The concomitant use of GINCOSAN and Efavirenz is therefore not recommended.

4.6. Fertility, pregnancy and lactation

There is limited amount of data from the use of Panax ginseng and Ginkgo biloba in pregnant women.
As a precautionary measure, it is preferable to avoid the use of GINCOSAN 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
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 either the Ginkgo biloba or 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: Other anti-dementia drugs
ATC code: N06DX
GINCOSAN is a combination of two extracts obtained from the leaves of the Ginkgo biloba tree (extract GK501) and the roots of Panax ginseng (extract G115), the exact mechanism of action is not known.
In an in vitro experiment conducted on human brain cerebral cortex membranes, ginseng has been shown to possess non-nicotinic receptor activities.
The ginkgoflavone glycosides and terpene lactones in the standardised Ginkgo biloba extract GK501 are thought to be responsible for its pharmacological effects; however, the complete extract must be considered as an active principle.
Clinical pharmacological studies have been performed in both ginseng and ginkgo extracts to study their effects on cerebral activities, blood glucose levels, on endothelial function, on blood and vessels, and on oxygen uptake. All these properties have a direct or indirect effect on cognitive functions.
The electroencephalograph effects of single doses of Ginkgo biloba extract GK501 and Panax ginseng extract G115 have been tested in healthy young volunteers. Results demonstrate for the first time that Panax ginseng can directly modulate cerebroelectrical activity, and that these effects are even more pronounced than those following Ginkgo biloba.
GINCOSAN has shown a number of activities in pre-clinical studies that suggest a favourable action on cognitive functions. The same applies to its components, the standardised Panax ginseng G115 and Ginkgo biloba extracts.
In a clinical pharmacological study the effects of GINCOSAN on hemorrheological and circulatory parameters have been investigated. Erythrocyte velocity in the capillary was increased with positive influence on blood fluidity and circulation.
The administration of GINCOSAN is able to increase the cerebrovascular blood flow speed in subjects during a clinical study.

Clinical efficacy and safety

Randomised controlled trials of GINCOSAN in humans have shown improvement in cognitive functions, particularly those related to memory and mental performance. Improvement was seen in a variety of mental tasks including the retention of information presented, improved mental endurance and mental capacity over time, together with reduced mental fatigability and forgetfulness. Positive changes in some parameters that are related to physical performance have also been observed.

5.2. Pharmacokinetic properties

Phytochemicals constituents mainly considered the responsible of pharmacological action are triterpene saponines (ginsenosides) for Panax ginseng and flavonoids and terpene trilactones for Ginkgo biloba.
Pharmacokinetic studies of individual purified constituents have been performed in various animal species with the standardised Panax ginseng G115 extract and Ginkgo biloba GK501 extract.
A pilot study demonstrated that after administration of 700 mg Panax ginseng G115 to healthy subjects ginsenosides subtypes that reached systemic circulation were Rb1, compound K and Rh1 and/or F1 and they were detectable in plasma 1 and 12 hours after dosing and in urine between 3 and 24 hours.
Following oral administration (as solution) of 120 mg of the Ginkgo biloba extract, the mean absolute bioavailability has been shown in humans for the terpene lactones ginkgolide A (80%), ginkgolide B (88%) and bilobalide (79%). Peak plasma concentrations of terpene lactones were in the range of 16-22 ng/ml for ginkgolide A, 8-10 ng/ml for ginkgolide B and 27-54 ng/ml when given as tablets. The corresponding half-lives of ginkgolide A and B and bilobalide were 3-4, 4-6 and 2-3 hours, respectively. 120 mg G. biloba extract given as solution peak plasma concentrations were 25-33 ng/ml, 9-17 ng/ml and 19-35 ng/ml for ginkgolide A, B and bilobalide, respectively. The related half-life for ginkgolide A was 5 hours, for ginkoglide B 9-11 hours and for bilobalide 3-4 hours.
The oral bioavailability of protopanaxadiol (PPD)-type saponins (ginsenosides Ra3, Rb1, Rd, Rg3, and Rh) and rotopanaxatriol (PPT)-type saponins (ginsenosides Rg1, Re, Rh1, and notoginsenoside R1) is less than 5%. Excretion of ginseng saponins at 0.2%–1.2% can be expected in human urine.
The time to reach maximum concentration (Tmax) in plasma and tissues is generally less than 2 h, indicating that ginseng saponins are rapidly absorbed and readily distributed in the tissues.

5.3. Preclinical safety data

No acute or chronic toxicity was observed with GINCOSAN or its individual components, the standardised Ginkgo biloba extract GK501 and Panax ginseng extract G115.
GINCOSAN and its components showed no teratogenic and embryotoxic effects in rats after oral administration of daily doses up to 6 g/kg.
No mutagenic effects of GINCOSAN were observed in the models tested.
No treatment related effects could be observed on reproduction and lactation of rats and rabbits after treatment with the standardised Ginseng extract G115.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose monohydrate; silica, colloidal anhydrous; mannitol; silicon dioxide; magnesium stearate; gelatine; titanium dioxide; iron oxide yellow; iron oxide red and purified water.

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

D552002.

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

9. DATE OF REVISION OF THE TEXT

May 2020