

เอกสารกำกับยาภาษาอังกฤษที่ขอแก้ไขเปลี่ยนแปลง

เอกสารกำกับยาภาษาอังกฤษที่ขอแก้ไขเปลี่ยนแปลง

(มีลักษณะและข้อความเหมือนกันทุกขนาดบรรจุ)

Giloba Ginkgo biloba extract 120 mg Capsules

Composition :

Each Softgel Capsule Contains :
Ginkgo biloba Extract 120 mg
Containing 24% of Ginkgo Glycosides and 6% of Ginkgolides and Bilobalide

Inactive ingredients :

Beewax white, Vegetable oil, Soybean oil, Gelatin, Glycerin, Purified water, Sunset Yellow, FD&C Green No.3, Iron oxide black, Titanium dioxide

Product description :

Oval, opaque green colored soft gelatin capsules filled with brown oily suspension

Pharmacodynamics :

Ginkgo effectively managed symptoms of cerebral insufficiency including difficulty in concentration and memory, absent-mindedness, confusion, lack of energy, tiredness, decreased physical performance, depressive mood, anxiety, dizziness, tinnitus and headache. Several mechanisms of action of Ginkgo have been described: effects on blood circulation such as the vasoregulating activity of arteries, capillaries, veins (increase blood flow); rheological effects (decrease viscosity, by PAF-receptor antagonism); metabolic changes such as increase tolerance to anoxia; beneficial influence on neurotransmitter disturbances; and prevention of damage to membranes by free radicals. Treatment of humans with Ginkgo extract has been shown to improved global and local cerebral blood flow and microcirculation, to protect hypoxia, to improve blood rheology, including inhibition of platelet aggregation, to improve tissue metabolism, and to reduce capillary permeability. The effectiveness of Ginkgo extract in the treatment of intermittent claudication (peripheral arterial occlusive disease Fontaine stage II) was demonstrated by a statistically significant increase walking distance. Improvement of vestibular and auditory functions was due to the effect of Ginkgo on the permeability and general microcirculation

Pharmacokinetics :

The pharmacokinetics and bioavailability of ginkgolides A and B and bilobalide were studied in 12 healthy young volunteers following oral (in fasting conditions and after a standard meal) single-dose administration of a standardized ginkgo leaf extract. The oral dose (120 mg of extract) corresponded to 1.44 mg of ginkgolide A, 1.03 mg of ginkgolide B and 3.36 mg of bilobalide. Plasma and urine samples collected for up to 36 and 48 hours were evaluated. When taken orally in fasting conditions, ginkgolides A and B and bilobalide showed a high bioavailability of 80, 88 and 79% respectively. After food intake the bioavailability of the three compounds was unchanged, except for the lag time in reaching peak concentration. Peak concentration in blood ranged from 16.5 to 33.3 ng/ml in fasting conditions, and from 11.5 to 21.1 ng/ml after a standard meal. The mean plasma elimination half-life was in the range of 9.5-10.6 hours for ginkgolide B and 3.2-4.5 hours for the other two compounds. Urinary excretion of ginkgolides A and B and bilobalide accounted for 72, 41 and 31% respectively of the administered oral dose in fasting conditions.

Indications :

- Improve cognitive function (such as memory) caused by cerebral insufficiency.
- Symptomatic treatment of mild or moderate dementia syndromes including primary degenerative dementia, vascular dementia and mixed forms, cerebral insufficiency.
- Neurosensory disturbances such as dizziness/vertigo and tinnitus.
- Symptomatic treatment of peripheral arterial occlusive disease (intermittent claudication).

Recommended Dose :

One capsule, once or twice daily before meals or as directed by physician.

Mode of Administration :

Oral Administration.

Contraindications :

Known hypersensitivity to any ingredient.

Warning and Precaution :

- Not advisable for pregnant and lactating women and children.
- Not advisable for patients with bleeding disorders.
- Ginkgo Extract should be use cautiously in patients with history of seizure because it may lower seizure threshold.
- Consider discontinuing Ginkgo Extract prior to elective surgery as it may increase the risk of postoperative bleeding.

Pregnancy and Lactation :

No data in human available. In accordance with general medical practice the product should not be used during pregnancy or lactation without careful consideration of the risk/benefit ratio.

Side Effects :

Ginkgo biloba extract is essentially devoid of any serious side effect. Mild headache lasts for a day or two; mild upset stomach and derma allergy have been reported in a very small percentage of people using Ginkgo biloba extract. However, if such symptoms occur, please consult with your physician or pharmacist.

Drug Interactions :

Ginkgo Extract may increase the risk of bleeding in individuals taking anticoagulants, antiplatelet, or nonsteroidal anti-inflammatory agents and increase the risk of sedation in patients taking trazodone. Caution is also advised if patients take Ginkgo Extract with the following medicines: anticonvulsants, buspirone, insulin, monoamine oxidase inhibitors, nifedipine, nifedipine, omeprazole, papaverine, St. John's Wort, selective serotonin reuptake inhibitors and thiazide diuretics.

Overdose & Treatment :

No significant adverse reactions have been reported in patients ingesting up to 600 mg of dry extract in single doses. However, Ginkgo Extract can act as a potent inhibitor of platelet-activating factor. Chronic use may be associated with increased bleeding time and the risk of spontaneous hemorrhage.

Dosage Forms & Packaging Available :

10 capsules in a blister pack, 3x10's packed in a light cardboard carton.

Storage Condition :

Store below 30°C in a dry place, away from direct sunlight

Note :

Read the instructions carefully before use.
Do not use the product after the expiry date.
Do not use the product if there are any significant changes in appearance of the capsules.
Keep out of reach of children.

Manufactured by :

MEGA LIFSCIENCES Public Company Limited
Samutprakarn, Thailand

Reg. No. 1A 33/64

Date of revision of the package insert : 21 May 2021

ส่วนขยายที่ 1

ส่วนขยายที่ 2

ส่วนขยายฉลากเอกสารกำกับยาภาษาอังกฤษที่ขอแก้ไขเปลี่ยนแปลง ส่วนที่ 1
(มีลักษณะและข้อความเหมือนกันทุกขนาดบรรจุ)

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ส่วนขยายฉลากเอกสารกำกับยาภาษาอังกฤษที่ขอแก้ไขเปลี่ยนแปลง ส่วนที่ 2 (มีลักษณะและข้อความเหมือนกันทุกขนาดบรรจุ)

and bilobalide were studied in 12 healthy young volunteers following oral (in fasting conditions and after a standard meal) single-dose administration of a standardized ginkgo leaf extract. The oral dose (120 mg of extract) corresponded to 1.44 mg of ginkgolide A, 1.03 mg of ginkgolide B and 3.36 mg of bilobalide. Plasma and urine samples collected for up to 36 and 48 hours were evaluated. When taken orally in fasting conditions, ginkgolides A and B and bilobalide showed a high bioavailability of 80, 88 and 79% respectively. After food intake the bioavailability of the three compounds was unchanged, except for the lag time in reaching peak concentration. Peak concentration in blood ranged from 16.5 to 33.3 ng/ml in fasting conditions, and from 11.5 to 21.1 ng/ml after a standard meal. The mean plasma elimination half-life was in the range of 9.5-10.6 hours for ginkgolide B and 3.2-4.5 hours for the other two compounds. Urinary excretion of ginkgolides A and B and bilobalide accounted for 72, 41 and 31% respectively of the administered oral dose in fasting conditions.

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Overdose & Treatment :

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Dosage Forms & Packaging Available :

10 capsules in a blister pack. 3x10's packed in a tight cardboard carton.

Storage Condition :

Store below 30°C in a dry place, away from direct sunlight

Note :

Read the instructions carefully before use.

Do not use the product after the expiry date.

Do not use the product if there are any significant changes in appearance of the capsules.

Keep out of reach of children.

Manufactured by :

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Samutprakam, Thailand

Reg. No. 1A 33/64

Date of revision of the package insert : 21 May 2021

ตารางแสดงการเปรียบเทียบข้อความที่ขอแก้ไขในเอกสารกำกับยาภาษาอังกฤษ

1. เอกสารกำกับยาภาษาอังกฤษ

รายละเอียดการแก้ไข	ฉลาก ณ ปัจจุบันที่ได้รับอนุมัติไว้	ฉลากที่ขอการแก้ไขเปลี่ยนแปลง
1.1 แก้ไขรายละเอียดในหัวข้อรูปแบบยา และขนาดบรรจุให้สอดคล้องกับที่ระบุบนเอกสาร ทย.1 ที่ได้รับอนุญาต	10 capsules in a blister pack. 3x10's packed in aluminium pouch and presented in a tight cardboard carton.	10 capsules in a blister pack. 3x10's packed in a tight cardboard carton.

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แก้ไขโดยตัดข้อความ
“in aluminium pouch and presented”