Tanakan®

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Brand name: Tanakan® (Танакан®)

Active substance: Ginkgo biloba leaf dry extract (EGb 761®)

Dosage form: Film-coated tablets, 40 mg; packs of 30 or 90 tablets

Presentation, packaging and composition

Brownish-red, round, biconvex film-coated tablets. When broken, the tablet core is light brown and has a

Composition	Per tablet
Ginkgo biloba leaf dry extract (EGb 761®)	40 mg
of which flavonol glycosides	22-27%
ginkgolides and bilobalide	5.4-6.6%

Excipients: lactose monohydrate 82.5 mg; microcrystalline cellulose, type 101, 50 mg; maize starch 37 mg; colloidal silicon dioxide 28 mg; talc 11.25 mg; magnesium stearate 1.25 mg.

Film-coating composition: macrogol 400, 1.5 mg; hypromellose (E464), 6 mg; macrogol 6000, 1.5 mg; titanium dioxide (E171), 1.025 mg; red iron oxide (E172), 0.65 mg.

Packaging: 15 tablets per blister. Cartons containing 2 or 6 blisters.

Clinical and pharmacological group

Herbal medicinal product that improves cerebral and peripheral circulation.

Pharmacotherapeutic group

Psychoanaleptics; anti-dementia drugs; other anti-dementia drugs.

Pharmacological action

Increases the body's resistance to hypoxia, especially in brain tissue. Improves cerebral and peripheral blood flow and blood rheology. Exerts a dose-dependent regulatory effect on the vascular wall, dilates small arteries and increases venous tone. Prevents free-radical formation and lipid peroxidation in cell membranes. Improves metabolism in organs and tissues, promotes the accumulation of high-energy compounds in cells, increases oxygen and glucose utilisation, and normalises neurotransmitter processes in the central nervous system.

Pharmacokinetics

Absorption

After oral administration, the bioavailability of terpene lactones (ginkgolide A, ginkgolide B and bilobalide) is 80% for ginkgolide A, 88% for ginkgolide B and 79% for bilobalide. Following oral administration as tablets, C_{max} is 16-22 ng/mL for ginkgolide A, 8-10 ng/mL for ginkgolide B and 27-54 ng/mL for bilobalide.

Distribution

Plasma protein binding is 43% for ginkgolide A, 47% for ginkgolide B and 67% for bilobalide.

Elimination

The elimination half-life ($T_{1/2}$) is 3.9 hours for ginkgolide A, 4-6 hours for ginkgolide B and 2-3 hours for bilobalide.

Therapeutic indications

- symptomatic treatment of cognitive impairment in adults;
- as adjunctive treatment, in addition to vestibular rehabilitation, as part of the combined treatment of vertigo of vestibular origin;
- symptomatic treatment of tinnitus (ringing or noise in the ears).

Dosage and administration

For oral use. Take during meals. Swallow the tablet with half a glass of water.

For adults receiving symptomatic treatment of cognitive impairment, vertigo of vestibular origin or tinnitus: 3 tablets per day, divided over the course of the day.

The treatment course should last at least 3 months. Treatment may be prolonged and repeated courses may be given on a doctor's recommendation.

Undesirable effects

Clinical studies demonstrated a favourable safety profile: the frequency of adverse reactions in the treatment group was not statistically higher than in the placebo group.

In the five-year GuidAge clinical study evaluating the efficacy and safety of Tanakan® 120 mg twice daily in patients over 70 years of age, the most common adverse reactions (>5%) were abdominal pain, diarrhoea and dizziness.

The table lists adverse reactions observed during clinical trials and post-marketing use of Tanakan®. Frequencies are defined as: common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100) and rare (≥1/10,000 to <1/1,000). Frequency estimates are based on the five-year GuidAge study.

System organ class	Frequency	Adverse reaction
Immune system disorders	Common	Hypersensitivity, dyspnoea
	Uncommon	Urticaria
	Rare	Angioedema (Quincke's oedema)
Central nervous system disorders	Common	Dizziness, headache, syncope
Gastrointestinal disorders	Common	Nausea, abdominal pain, diarrhoea, dyspepsia
Skin and subcutaneous tissue disorders	Common	Eczema, pruritus
	Uncommon	Rash

Contraindications

- hypersensitivity to any component of the product;
- reduced blood coagulation;
- erosive gastritis during an acute exacerbation;
- gastric or duodenal ulcer during an acute exacerbation;
- acute cerebrovascular disorders;
- acute myocardial infarction;
- lactose intolerance, lactase deficiency or glucose-galactose malabsorption syndrome;
- age under 18 years (efficacy and safety have not been established).

Use with caution

- when EGb 761® is taken concomitantly with medicines metabolised by the CYP3A4 isoenzyme that have a narrow therapeutic index;
- in patients with epilepsy.

Pregnancy and breast-feeding

Pregnancy

Only limited data are available on the use of Tanakan® in pregnant women. Experimental animal studies did not indicate direct or indirect harmful effects with respect to reproductive toxicity. Because sufficient clinical data are unavailable, use during pregnancy is contraindicated.

Breast-feeding

It is unknown whether Tanakan® passes into animal or human milk. A decision must be made whether to discontinue breast-feeding or to discontinue therapy, taking into account the benefit of breast-feeding for the newborn/infant and the benefit of therapy for the woman.

Use in children

Use is contraindicated in children and adolescents under 18 years of age because efficacy and safety have not been established.

Special warnings and precautions

Do not exceed the recommended doses. The medicine may be taken in repeated long-term courses.

Discontinue use if a hypersensitivity reaction develops.

Tell your doctor that you are taking this medicine before surgery.

Consult a doctor if dizziness or tinnitus occurs frequently. Seek immediate medical attention if hearing suddenly worsens or is lost.

Patients with a bleeding tendency (haemorrhagic diathesis) and patients receiving anticoagulant therapy must consult a doctor before starting treatment.

Concomitant use with ethanol is not recommended.

Caution is recommended during concomitant use of medicines metabolised by cytochrome P450, including CYP3A4 (see Interactions with other medicinal products).

Tanakan® contains lactose. Patients with hereditary lactose intolerance, lactase deficiency or glucose-galactose malabsorption syndrome should not take this dosage form.

Epileptic seizures may occur during treatment in patients with epilepsy.

Effects on ability to drive and use machines

No studies have been conducted on the effects on the ability to drive or use machines.

During treatment, caution should be exercised when performing potentially hazardous activities that require increased concentration and rapid psychomotor responses, including driving and operating moving machinery. If adverse reactions such as dizziness develop, do not drive.

Overdose

There is no substantial experience of overdose with this medicine. If overdose occurs, treatment should be symptomatic.

Interactions with other medicinal products

Use with caution in patients who regularly take acetylsalicylic acid, anticoagulants (direct or indirect), thiazide diuretics, tricyclic antidepressants, anticonvulsants or gentamicin.

Isolated cases of bleeding have been reported in patients concomitantly taking medicines that reduce blood coagulation. A causal relationship between such bleeding and the use of Ginkgo biloba products has not been confirmed.

Concomitant use of Ginkgo biloba products with efavirenz is not recommended because induction of CYP3A4 by Ginkgo biloba extract may reduce the plasma concentration of efavirenz.

An interaction study with talinolol indicates that Ginkgo biloba extract may inhibit intestinal P-glycoprotein. This may increase exposure to medicines that are sensitive to intestinal P-glycoprotein, such as dabigatran; caution is therefore required during concomitant use.

Storage conditions

Keep out of the reach of children. Store below 25°C.

Shelf life

3 years. Do not use after the expiry date stated on the package.