APPROVED
The Order of the Ministry
of Health of Ukraine
02.10.2019 No.2004
Registration Certificate
No.UA/3384/01/01

INSTRUCTION
for medical use of medicinal product
LEKNIZINE®

УТВЕРЖДЕНО
Приказ Министерства
здравоохранения Украины
02.10.2019 №2004
Регистрационное удостоверение
№UA/3384/01/01

ИНСТРУКЦИЯ
по медицинскому применению
лекарственного средства
ЦИННАРИЗИН
(CINNARIZINE)

Composition:
active ingredient: cinnarizine;
Each tablet contains 0.025 g cinnarizine (25 mg);
excipients: lactose monohydrate, potato starch, magnesium stearate, anhydrous colloidal silicon dioxide, povidone.

Pharmaceutical form. Tablets.
Basic physical and chemical properties: white or off-white tablets.

Pharmacotherapeutic group. Antivertigo preparations. ATC code N07C A02.

Pharmacological properties.
Pharmacodynamic properties.
Cinnarizine inhibits the smooth muscle contractions through calcium channel blocking. In addition to direct calcium antagonism, cinnarizine reduces the contractile action of vasoactive agents, such as norepinephrine and serotonin, by blocking receptor-operated calcium channels. Blockade of calcium influx into the cells is selective in the tissues and leads to a decrease in vasoconstriction without any effect on the blood pressure and heart rate.
Cinnarizine can further improve insufficient microcirculation by increasing the elasticity of the erythrocyte membrane and reducing blood viscosity. Administration of cinnarizine increases cellular resistance to hypoxia.
Cinnarizine inhibits stimulation of the vestibular system, which leads to suppression of nystagmus and other autonomic disorders. Cinnarizine prevents or alleviates acute attacks of dizziness.
Pharmacokinetic properties.
Absorption. Maximum cinnarizine plasma concentrations are achieved approximately in 1 to 3 hours after oral administration.
Distribution. The plasma protein binding is 91%.
Biotransformation. Cinnarizine is metabolised mainly via CYP2D6.
Elimination. The reported elimination half-life for cinnarizine ranges from 4 to 24 hours. The elimination of metabolites occurs as follows: 1/3 in the urine and 2/3 in the faeces.

Clinical particulars.
Therapeutic indications.
Cerebrovascular disorders:
– symptomatic treatment of cerebrovascular disorders, including dizziness, tinnitus, headache of vascular origin, irritability, memory loss, and inability to concentrate;
– migraine prevention.
Peripheral circulation disorders:
– symptomatic treatment of peripheral vascular disorders, including Raynaud's disease, acrocyanosis, intermittent lameness (Charcot disease), trophic disorders, trophic and varicose ulcers, paraesthesia, nocturnal spasms in the extremities, cold extremities.
Balance disorder:

– symptomatic treatment of labyrinth disorders, including dizziness, tinnitus, nystagmus, nausea, and vomiting.
Motion sickness:
– prevention of motion sickness.

Contraindications.
Hypersensitivity to active ingredient or any excipients of the medicinal product.

Interaction with other medicinal products and other forms of interaction.
Alcohol/central nervous system (CNS) depressants/tricyclic antidepressants: concurrent use may potentiate the sedative effects of either these drugs or of Leknizine®.
Diagnostic procedures: Due to its antihistamine effect, Leknizine® may prevent otherwise positive reactions to dermal reactivity indicators; for this reason, it is recommended to withhold its administration in 4 days prior to testing.

Special warnings and precautions for use.
Leknizine® may cause epigastric discomfort; taking it after meals may diminish the gastric irritation.
In patients with Parkinson's disease, Leknizine® should only be recommended if the advantages outweigh the possible risk of aggravating this disease.
Since Leknizine® is known to cause drowsiness, especially at the beginning of treatment, it is recommended to avoid combined consumption of alcohol and the use of agents known to inhibit the activity of the CNS (CNS depressants) or tricyclic antidepressants.
Use of Leknizine® should be avoided in porphyria.
Leknizine® should be used with care in patients with hepatic and/or renal insufficiency.
This product contains lactose and therefore should not be prescribed in patients with rare hereditary galactose intolerance, lactase deficiency or glucose-galactose malabsorption syndrome.
Fertility, pregnancy and lactation.
Pregnancy. The medicinal product is not recommended for administration in pregnancy.
Breast-feeding. There are no data on the excretion of cinnarizine in human breast milk. Thus, the use of the medicinal product should be avoided in nursing mothers.
Effects on ability to drive and use machines.
Given that sensitive patients may experience drowsiness when taking the drug (especially at the beginning of treatment), it is recommended to avoid driving and performing other works requiring attention and focus while taking the drug.

Posology and method of administration.
Cerebrovascular disorders.
Adults and children over 12 years of age: 1 tablet t.i.d.
Peripheral circulation disorders.
Adults and children over 12 years of age: 2-3 tablets t.i.d. The maximum recommended dose should not exceed 225 mg (9 tablets) per day. Since in cases of dizziness the effect is dose-dependent, the dosage should be gradually increased.
Balance disorder.
Adults and children over 12 years of age: 1 tablet t.i.d.
Motion sickness.
Adults and children over 12 years of age: 1 tablet 30 minutes before you travel; and every 6 hours during your journey.
Method of administration.
For oral use. Cinnarizine shall be preferably taken after meals.

Paediatric population. Cinnarizine shall be administered in children over 12 years of age.

Overdose.

Symptoms. In isolated instances of acute overdose (doses ranging from 90 to 2.250 mg) the following manifestations were observed: alterations in consciousness ranging from somnolence to stupor and coma, vomiting, extrapyramidal symptoms, and hypotonia. In a small number of children, seizures developed. Clinical consequences were not severe in most cases, but deaths have been reported after single and polydrug overdoses involving cinnarizine.
Treatment. There is no specific antidote. Gastric lavage should be performed within one hour after oral administration of the medicinal product. It is possible to prescribe activated carbon, if medically required.

Undesirable effects.
Drowsiness and GIT disorders have been observed. Typically these symptoms are transient in nature and resolve when the optimum dose is gradually reached. Such symptoms as headache, dry mouth, weight gain, profuse sweating, hypersensitivity (allergic reactions), and cholestatic jaundice are rare. Wilson's lichen and lupus symptoms have been reported very occasionally. In the medical literature, an isolated case of obstructive jaundice was mentioned.
With prolonged treatment, elderly patients have experienced exacerbation or onset of extrapyramidal symptoms, sometimes combined with depressive conditions. In such cases, the medicinal product should be discontinued.
Frequencies displayed use the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Nervous system disorders	
Common	somnolence
Uncommon	hypersomnia, lethargy
Not known	dyskinesia, extrapyramidal disorders, parkinsonism, tremor
Gastrointestinal disorders	
Common	nausea, dyspepsia
Uncommon	gastrointestinal upset, vomiting, upper abdominal pain
Hepatobiliary disorders	
Not known	cholestatic jaundice
Skin and subcutaneous tissue disorders	
Uncommon	hyperhydrosis, lichenoid keratosis including lichen planus
Not known	subacute cutaneous lupus erythematosus
Musculoskeletal and connective tissue disorders	
Not known	Muscle rigidity
General disorders and administration site conditions	
Uncommon	fatigue
Investigations	
Common	weight gain

Additionally, cases of hypersensitivity, headache, and dry mouth have been reported.

Shelf life. 5 years.

Storage. Keep away from children. Store in original package at temperature not exceeding 25 °C.

Package. 10 tablets in a blister; 5 blisters in a pack.

Prescription status. By prescription.

Manufacturer. Joint Stock Company «Lekhim-Kharkiv».

Location. Ukraine, 61115, Kharkiv region, Kharkiv, Severyna Pototskoho street, building 36.

Date of the last revision.