APPROVED
Order of Ministry of
Healthcare of Ukraine
20.11.2018 No. 2142
Registration Certificate
No. UA/9290/01/01

INSTRUCTION
for medical use

WOLVIT®

Composition:
active substance: biotin;
1 tablet contains biotin 5 mg;
excipients: celactose 80, sodium lauryl sulfate, sodium croscarmellose, colloidal silicon dioxide anhydrous, magnesium stearate, covering Insta Moistshield Aqua II A22R01063*.
* – Coating material Insta Moistshield Aqua II A22R01063: polyvinyl alcohol, talc, titanium dioxide (E 171), polyethylene glycol, lecithin, Lake Erythrosine (E 127), Yellow Iron Oxide (E 172).

Pharmaceutical form. Film coated tablets.
Basic physico-chemical properties: round biconvex pink film coated tablets.

Pharmacotherapeutic group. Other plain vitamin preparations. Biotin.
Code ATC A11H A05.

Pharmacological properties.
Pharmacodynamics.
Biotin (vitamin H, vitamin B_7) is a water-soluble vitamin of B group. In human body it plays an important role in metabolism of carbohydrate, fatty acids and proteins, and it is essential for normal cells growth and development. When ingested, biotin serves as a coenzyme of carboxylases, has an insulin-like effect and participates in the process of gluconeogenesis (due to participation in the synthesis of glucokinase), as a result of which it contributes to the stabilization of blood sugar, improves the function of the nervous system. Biotin is a synergist of other B vitamins, folic acid, pantothenic acid, and cyanocobalamin. There are data on the participation of biotin in the synthesis of purine nucleotides. Biotin is also a source of sulfur, which participates in the synthesis of protein collagen, and thus has a positive effect on the structure of the skin and its appendages (hair, nails). Biotin deficiency can occur with an unbalanced diet, long-term diets and the use of raw egg white; with parenteral nutrition; with malabsorption syndrome, after resection of the small intestine; with biotin-associated multiple carboxylase insufficiency; in patients undergoing hemodialysis.
Pharmacokinetics.
In the body, biotin is quickly absorbed in the small intestine by passive diffusion, after which it enters the liver through the portal system and then into the systemic bloodstream. The degree of binding of biotin to blood plasma proteins is 80%. The concentration of free or weakly bound biotin in the blood is, as a rule, from 200 to 1200 μg/l. Biotin passes through the blood-brain and placental barriers. It is metabolized in the body with the formation of various metabolites. Biotin is excreted with urine (from 6 to 50 μg per day) and feces in unchanged form (about 50%), as well

as in the form of biologically inert metabolic products. The half-life depends on the volume of the injected dose and is about 26 hours after the introduction of a dose of 100 μg per kg of body weight. In patients with biotinidase deficiency, the half-life after administration of the same dose is reduced to 10–14 hours.

Indications.
Treatment of diseases caused by biotin deficiency: a disease of the skin, nails, hair.
Treatment of genetically caused biotin-associated enzymopathies (multiple carboxylase deficiency).

Contraindications.
Hypersensitivity to biotin or other drug components.

Interaction with other medicinal products and other forms of interaction.
When biotin is used with anticonvulsants, the plasma concentration of biotin can be decreased due to its increased excretion with urine. Valproic acid reduces activity of biotinidase by diminishing the functions of mitochondria in the liver.
The raw egg white contains protein avidin which co-operates with biotin; therefore it is necessary to avoid their simultaneous use. Eating large amounts of raw eggs for 2–3 weeks can cause biotin deficiency.
Pantothenic acid in large doses competes with biotin, so their simultaneous use should be avoided.

Special warnings and precautions for use.
Do not violate the duration of the course of treatment prescribed by the doctor. In the case of intermittent or prematurely stopped treatment, the effect of the drug may decrease. Due to the good tolerance of biotin, the treatment can be continued for a long time.
Influence on the results of clinical laboratory studies.
Biotin may interfere with the results of clinical laboratory studies that rely on the interaction of biotin/streptavidin, leading to false underestimation or overestimation of data, depending on the type of study. The risk of such exposure is higher in children and in patients with impaired renal function, and also increases with increasing doses of biotin. When interpreting the results of studies, the possible influence of the use of biotin by the patient should be taken into account, especially if such data are inconsistent with the existing clinical picture (for example, false-positive results of the study of the thyroid gland function in Graves disease or false-negative results of the troponin level in patients with myocardial infarction). When planning clinical laboratory tests in patients taking biotin, the appropriate laboratory specialists should be consulted beforehand. In those cases where the possibility of biotin influence on research results is not excluded, it is necessary to use alternative tests that do not depend on this factor.

Excipients.
The drug contains Ponceau 4R (E 124), therefore it may cause allergic reactions.

Use during pregnancy or lactation.
There is no experience of using the drug during pregnancy and lactation.

Effects on ability to drive a car or use machines.
There is no data on the negative effect of the drug on the speed of psychomotor reactions.

Administration and dosage.
Wolvit® should be used orally by adults. Take before meals with a small amount of water.
Diseases of nails, hair and skin: the recommended dose is 5 mg (1 tablet) of biotin per day.

Genetically caused biotin-associated enzymopathies (multiple carboxylase deficiency): 2–4 tablets (daily dose – up to 20 mg of biotin) in 1–2 doses per day.
The duration of the treatment course depends on the nature and course of the disease and is usually 1 month.

Children.
The drug is not intended for use in children.

Overdose.
There are currently no reports of biotin overdose.

Adverse reactions.
Immune system disorders: allergic reactions are possible, including urtricaria, chest pain, shortness of breath, skin rashes.
In the event of any adverse reaction, it is recommended to discontinue treatment and seek medical advice.

Shelf life. 4 years.

Storage conditions.
Store in the original package at the temperature not exceeding 25°C.
Keep out of reach of children.

Package.
10 tablets in a blister, 3 blisters in a carton box.

Condition of supply. Without prescription.

Manufacturer.
KUSUM HEALTHCARE PVT LTD.

Manufacturer's location and address of the place of business.
Plot No. M-3, Indore Special Economic Zone, Phase-II, Pithampur, Distt. Dhar, Madhya Pradesh, Pin 454774, India.

Date of last revision. 19.03.2024