Clenbuterol® tablets

Registration number:
LP-001173 (ЛП-001173)

Trade name:
Clenbuterol Sopharma

International nonproprietary name (INN):
Clenbuterol

Dosage form:
Tablets

Composition per tablet:
Active ingredient: Clenbuterol hydrochloride 0.02 mg
Excipients: Lactose monohydrate – 70.00 mg, wheat starch – 31.48 mg, microcrystalline cellulose – 48.50 mg, colloidal silicon dioxide – 2.00 mg, magnesium stearate – 2.00 mg, povidone (povidone K25) – 6.00 mg.

Description:
Round, flat tablets with a beveled edge and a score line on one side, white or almost white in color.

Pharmacological group:
Bronchodilator – selective beta-2-adrenomimetic

Atc code:
[R03CC13]

Pharmacological properties:

Pharmacological action:
A selective beta-2 adrenostimulator that provides bronchodilatory and secretolytic effects. It stimulates $beta_2$-adrenoreceptors, activates adenylate cyclase, increases cellular cyclic adenosine monophosphate (cAMP) content, which affects the protein kinase system, resulting in myosin losing its ability to bind with actin, leading to bronchodilation. It inhibits the release of mediators from mast cells that cause bronchospasm and bronchial inflammation.
Prevents bronchospasm caused by histamine, serotonin, and acetylcholine. Reduces bronchial edema or congestion, improves mucociliary clearance. The secretolytic action is associated with reduced sputum viscosity and easier expectoration. Causes vasodilation in the brain and skeletal muscles. Has tocolytic effects. Side effects are related to its ability, albeit weak, to stimulate cardiac $beta_1$-adrenoreceptors, resulting in positive ino- and chronotropic effects.
Has minor anabolic effects and may increase body temperature.
Maximum effect is observed after 2-3 hours and lasts for 6-8 hours.

Pharmacokinetics:
Rapidly and completely absorbed in the gastrointestinal tract. Metabolized to a minor extent in the liver, forming 8 metabolites that have no pharmacological activity.
Plasma elimination occurs in two phases. The half-life of the first phase is 1 hour, the second – 34 hours. Mainly excreted unchanged through the kidneys, with 87% of the administered dose eliminated within 168 hours.

Indications:
Chronic obstructive pulmonary disease, broncho-obstructive syndrome, bronchial asthma.

Contraindications:
Hypersensitivity to clenbuterol or excipients
Thyrotoxicosis
Tachyarrhythmia
Hypertrophic obstructive cardiomyopathy
Acute phase of myocardial infarction
Severe coronary artery disease
Lactase deficiency
Lactose intolerance
Glucose-galactose malabsorption
Children under 6 years
Pregnancy (1st and 3rd trimesters)

Use with caution:
Hyperthyroidism, history of myocardial infarction, coronary artery disease, arterial hypertension, prostatic hypertrophy, diabetes mellitus, 2nd trimester of pregnancy.

Pregnancy and lactation:
Avoid use in the first 3 months of pregnancy due to possible adverse effects on fetal development. Not recommended in the last months of pregnancy and during labor due to tocolytic effects and possible suppression of uterine tone. No specific clinical studies on transfer to breast milk have been conducted, therefore not recommended during breastfeeding.

Dosage and administration:
Oral use.

Adults:
0.02 mg (one tablet) twice daily (morning and evening). Maintenance dose 0.01 mg (½ tablet) twice daily. In more severe conditions, initially 0.04 mg (two tablets) twice daily (morning and evening). Dose should be reduced after improvement.

Children:
Ages 6-12: 0.01 mg (½ tablet) twice daily (morning and evening)
Over 12 years: 0.01 mg (½ tablet) 2-3 times daily or 0.02 mg (1 tablet) twice daily (morning and evening)

Side effects:

Central nervous system:
Fear, mental disturbances, hyperkinesis, sleep disorders, headache, facial flushing, sweating, tremors and anxiety, dizziness; may worsen tremors and muscle rigidity in Parkinson's disease patients.

Cardiovascular system:
Palpitations, tachycardia, blood pressure changes (usually increase), myocardial ischemia.

rinary system:
Urinary retention related to renal vessel and bladder sphincter spasm.

Metabolism:
May cause hyperglycemia in diabetic patients due to glycogenolysis stimulation. Dose reduction without discontinuation is required if this occurs.

Digestive system:
Dry mouth, nausea.

Allergic reactions:
Skin rash, urticaria.

Other:
Hypokalemia.

Overdose:
Manifests as intensified side effects: arrhythmia, tachycardia, increased blood pressure, cardialgia, limb tremors. Risk of hypokalemia after overdose requires monitoring of serum potassium levels.
Treatment: Gastric lavage, activated charcoal, saline solutions, symptomatic treatment (including cautious use of selective beta-blockers).

Drug interactions:
Beta-blockers may reduce or eliminate bronchodilatory effect
Reduces hypoglycemic medication effects
Increased risk of cardiac arrhythmias with cardiac glycosides, MAO inhibitors, and theophylline
Reduces effectiveness of antihypertensive drugs
Effects potentiated by tricyclic antidepressants, beta-adrenomimetics, and anticholinergic agents
Mutual toxicity increase with sympathomimetic drugs
Halothane and other halogenated hydrocarbon anesthetics, and cyclopropane may potentiate proarrhythmogenic effects of β_2-adrenomimetics, including clenbuterol

Special instructions:
Regular blood glucose monitoring required in diabetic patients. May increase body weight due to anabolic effects and may cause positive doping test results in athletes.
Like other sympathomimetics, may cause cardiovascular side effects

including myocardial ischemia. Patients with cardiovascular diseases should be advised to seek medical attention if chest pain or other symptoms worsen.
Development of resistance and rebound syndrome possible during treatment.
Contains wheat starch with trace amounts of gluten, considered safe for celiac patients.

Effect on ability to drive and use machinery:

Due to possible tremors, dizziness, and weakness, avoid potentially dangerous activities requiring attention and quick reactions during treatment.

Form of release:

0.02 mg tablets. 10 tablets per PVC/aluminum foil blister. 5 blisters with instructions in a cardboard box.

Storage conditions:

Store at temperature not exceeding 25°C. Keep out of reach of children!

Shelf life

3 years. Do not use after expiration date.

Dispensing conditions:

Prescription only

Manufacturer name and address:

SOPHARMA AD 16 Iliensko Shose Str., 1220 Sofia, Bulgaria

This instructions was translated from the official manufacturer's instructions in Russian by Extrapharma Online Pharmacy.