

Doxitus 100 mg/ml

Pharmaceutical form: Oral syrup

Ingredients: 5 ml contains: Active ingredient – 100 mg Doxofylline.

Excipients: Sucrose, saccharine sodium, ammonium glycyrrhizinate, sodium methyl-p-hydroxybenzoate, sodium propyl-p-hydroxybenzoate, aromatizators (caramel, menthol), purified water.

Pharmacological group: other drugs for the treatment of obstructive respiratory diseases, for systemic use. Derivatives of xanthine.

Pharmacodynamics:

Doxitus is bronchodilator, derivative of xanthine.

Doxitus causes phosphodiesterase suppression – an enzyme that degrades cAMP.

As a result of the accumulation of cAMP, the concentration of free calcium in bronchial myocytes decreases (the bronchial muscles relax) and in mast cells, which, in turn, leads to a decrease in the release of histamine and serotonin from them, and other substances leading to bronchial spasm and swelling of their mucous membranes. It also blocks adenosine 1 (purine 1) receptors on bronchial smooth muscle cells, causing them to relax, and on sympathetic presynaptic endings, inhibiting the release of norepinephrine.

Pharmacokinetics:

After oral administration, the maximum plasma concentration in blood is reached after 1 hour. Absolute oral bioavailability is 62.6%. Binding to plasma proteins is about 48 %. Doxofylline is thought to undergo hepatic metabolism (90%) by acidifying and dimethylation with enzymes of microsomal acidifying (cythichrome P-450) and xanthinoxidase.

Doxofylline half-life period with a single use is more than 7 hours, and with long-term use - 8-10 hours. After secondary use doxofylline reaches the steady-state in about 4 days.

Doxofylline is almost completely metabolized in the liver (90%) in inactive form, and less than 4% and less than 4% unchanged in the urine.

Indications:

- bronchial asthma
- chronic obstructive pulmonary disease (COPD).

Contraindications:

- hypersensitivity to drug components;
- breastfeeding period;
- children under 3 years of age.

Dosage and administration

Children

The dose is depended on the child body weight and is determined by the attending physician.

The recommended daily dose of Doxofylline for children is 12 mg/kg, divided into two doses. The dose can be increased up to 18 mg/kg.

Adults: 20 ml (400 mg) twice a day. The dose can be increased up to 20 ml (400 mg) 3 times/daily.

Elderly: 10 ml (200 mg) twice a day.

It is not recommended to take a double dose to make up for the missed dose, and also to stop treatment with the drug at your own discretion.

Warnings and precautions:

Doxitus is applied with caution to patients with hypertension, insufficient oxygen in the blood (hypoxemia), hyperthyroidism (hyperthyroidism), chronic right ventricular failure, congestive heart failure, liver disease, kidney disease, with anamnesis of peptic ulcer, and in elderly patients with impaired liver function: in case of sugar intolerance.

The drug contains sodium methyl-p-hydroxybenzoate and sodium propyl-p-hydroxybenzoate, which can cause allergic reactions (including delayed reactions).

Pregnancy and breastfeeding:

Doxitus can be given to pregnant women if the benefit to the mother outweighs the risk to the fetus.

Doxitus is not recommended to use during the period of breastfeeding.

Adverse reactions:

It is possible to observe such occurrence as nausea, vomiting, pain in the epigastric region, headache, irritability, insomnia, tachycardia, heart rhythm disturbance (the appearance of extrasystoles), tachypnea, rarely hyperglycemia and proteinuria.

Low doses of repeated administration of the drug can be started only after consultation with your doctor.

Packaging:

100 ml glass bottle with dosage spoon and Patient Information Leaflet completed in a Paperboard box.

Shelf life:

2 years.

Storage conditions:

Store at temperatures between 5°C to 25°C. Keep out of reach of children.

Regulatory status:

Prescription only.