

PACKAGE LEAFLET
for medical use of a medicinal product

Ritosse® Ivy

Qualitative and quantitative composition:

Active substance: hederæ helicis folium;

1 ml of syrup contains 7 mg of ivy leaf dry extract (Extr. Hederae helicis e folium spir. sicc. ((4–8): 1), (extragent: ethanol 30%);

list of excipients: potassium sorbate; citric acid monohydrate; liquid sorbitol that does not crystallize; xanthan gum; purified water;

1 ml of syrup contains 550 mg of the sugar substitute sorbitol, which corresponds to 0,04 bread units.

Pharmaceutical form. Syrup.

Main physical and chemical properties: light brown, slightly turbid, viscous liquid with a specific odor. Presence of sediment is allowed.

Pharmacotherapeutic group. Cough and cold preparations. Expectorants. ATC code R05C A12.

Pharmacological properties.

Pharmacodynamic properties

The medicinal product of herbal origin, contains glycosidic saponins, which cause antitussive, expectorant, antispasmodic and antimicrobial effects. Reduces the viscosity of sputum, facilitates its discharge.

Pharmacokinetic properties

Not studied.

Clinical particulars.

Therapeutic indications.

Acute inflammatory diseases of the respiratory tract, accompanied by a cough.

Chronic inflammatory diseases of the bronchi - symptomatic treatment.

Contraindications.

Hypersensitivity to the active substance, plants of the Araliaceae family, or to any other component of the medicinal product. Fructose intolerance.

Interaction with other medicinal products and other forms of interaction

Concomitant use with antitussive medicinal products, such as codeine or dextromethorphan, is not recommended without consulting a doctor.

No adverse reactions of Ritosse® Ivy, syrup were observed with concomitant use of other medicinal products. Therefore, this medicinal product can be administered with other medicinal products, such as antibiotics.

Special warnings and precautions for use.

Children under 2 years of age should take Ritosse® Ivy, syrup only under close medical supervision in a hospital setting.

Prolonged or recurrent cough in children under 4 years of age requires a medical diagnosis before treatment. If symptoms persist or shortness of breath, high temperature, fever, purulent or bloody sputum appear when coughing up, consult a doctor immediately.

Concomitant use with antitussive medicinal products, such as codeine or dextromethorphan is not recommended without medical advice.

Use with caution in patients with gastritis or gastric ulcer.

Important information about excipients.

This medicinal product contains potassium compounds. Caution should be exercised when using in patients with impaired renal function or those who follow a low-potassium diet.

Ritosse® Ivy, syrup contains sorbitol. If you have a history of intolerance to some sugars, consult your doctor before taking this medicinal product.

Fertility, pregnancy and lactation.

Due to the lack of research data, this medicinal product should not be taken during pregnancy or lactation.

Effects on ability to drive and use machines

The medicinal product does not affect the reaction rate when driving or operating other machines.

Posology and method of administration.

Ritosse® Ivy, syrup, apply orally, measuring out the dose with the supplied measuring spoon. Children aged 1 to 6 years - 2.5 ml twice daily, children 6 to 12 years - 5 ml twice daily, adults and children over 12 years old - 5 ml 3 times a day (in the morning, afternoon and evening).

The duration of treatment is determined by the doctor individually. In simple cases, the duration of treatment is 1 week. To achieve a stable therapeutic effect, it is recommended to continue therapy for another 2-3 days after the patient's condition improves.

Shake the syrup thoroughly before each use!

If the patient's condition does not improve, a doctor should be consulted for further treatment.

Children.

Ritosse® Ivy, syrup, is used in children aged 1 year and older. For children under 2 years of age, the medicinal product is used under close medical supervision in a hospital setting.

Overdose.

Doses in excess of the recommended may cause nausea, vomiting, diarrhea or agitation. Treatment is symptomatic.

Undesirable effects.

Very rare (less than 1 case per 10,000) there may be a laxative effect (due to the sorbitol content), as well as allergic reactions: shortness of breath, swelling of the mucous membranes, skin rash, urticaria, itching.

Gastrointestinal disorders, including nausea, vomiting, diarrhea, and abdominal pain, may occur in patients with hypersensitivity.

Reported suspected adverse reactions.

Reporting suspected adverse reactions after registration of a medicinal product is an important procedure. This allows for continued monitoring of the benefit/risk ratio for the respective drug. Healthcare providers should be informed of any suspected adverse reactions through the national alert system.

Shelf life. 1,5 years.

After opening the vial, the medicinal product can be used for 3 months.

Special precautions for storage.

Store in the original package at a temperature not exceeding 25°C. Keep out of the reach of children.
During storage, slight turbidity and a slight change in the taste of the syrup are possible, which does not affect the therapeutic properties of the medicinal product.

Nature and content of container.

100 ml in a vial, 1 vial with a measuring spoon in a pack.

Category of release. Non-prescription medicine.

Manufacturer PrJSC “Pharmaceutical firm “Darnitsa”.

The manufacturer's location and address of the place of business.

13, Boryspilska Street, Kyiv, 02093, Ukraine.

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