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Levodropropizina Eg Cough Syrup 200 ml

EG

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Syrup based on **levodropropizina** .

Therapeutic indications

Levodropropizina Eg Syrup is used in the symptomatic treatment of cough.

Dosage and Posology

The drug should be taken according to the following doses and methods. The package includes a measuring cup with notches corresponding to 3, 5 and 10 ml. To open the package it is necessary to press the cap firmly and turn counterclockwise at the same time.

- Adults: 10 ml of syrup up to 3 times a day at intervals of at least 6 hours.
- Children: 10-20 kg 3 ml 3 times a day; 20-30 kg 5 ml 3 times a day.

Treatment should be continued until the cough subsides or as directed by the doctor. However, if the cough is still present after 2 weeks of therapy, it is advisable to stop the treatment and ask your doctor for advice. In fact, cough is a symptom and the causal pathology should be studied and treated.

Overdose

No significant side effects have been reported after drug administration up to 240 mg single dose and up to 120 mg tid for 8 consecutive days. There is only one known case of overdose in a 3 year old child treated with a daily dose of 360 mg levodropropizin. The patient experienced non-severe abdominal pain and vomiting which resolved without sequelae. In case of overdose with evident clinical manifestations, immediately institute symptomatic therapy and apply the usual emergency measures (gastric lavage, activated charcoal meal, parenteral administration of liquid, etc.), if necessary.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients
- Administration of the drug should be avoided in patients with bronchorrhea and with reduced mucociliary function (Kartagener's syndrome, ciliary dyskinesia).
- Pregnancy and breastfeeding

Side effects

The experience derived from the marketing of products containing levodropropizin in more than 30 countries around the world shows that the appearance of undesirable effects is a very rare event. Based on the estimate of patients exposed to levodropropizin, derived from the number of packs sold, and considering the number of spontaneous reports, less than one patient in 500,000 experienced adverse reactions. Most of these reactions are not severe and symptoms resolved with discontinuation of therapy and, in some cases, with specific drug treatment.

The adverse reactions found, all very rare (incidence <1 / 10,000) are the following:

- Skin and appendages: urticaria, erythema, rash, pruritus, angioedema, skin reactions. A single case of epidermolysis with fatal outcome has been reported.
- Digestive system: gastric and abdominal pain, nausea, vomiting, diarrhea. Two single cases of glossitis and aphthous stomatitis have been reported, respectively. One case of cholestatic hepatitis and one case of hypoglycemic coma have been reported in an elderly patient treated concomitantly with oral hypoglycemic agents.
- General conditions: allergic and anaphylactoid reactions, general malaise. Single cases of generalized edema, syncope and asthenia have been reported, respectively.
- Nervous system: dizziness, vertigo, tremors, paraesthesia. A single case of tonic-clonic seizure and one case of a petit mal attack have been reported.
- Cardiovascular system: palpitations, tachycardia, hypotension. One case of cardiac arrhythmia (atrial bigeminy) has been reported.
- Psychiatric disorders: nervousness, drowsiness, sense of depersonalization.
- Respiratory system: dyspnoea, cough, edema of the respiratory tract.
- Musculoskeletal system: asthenia and weakness of the lower limbs.

Few cases of eyelid edema have been reported, most of which refer to angioneurotic edema, considering the concomitant presence of urticaria. A single case of mydriasis and a case of bilateral vision loss have been reported. In both cases the reaction resolved after discontinuation of the drug. A single case of somnolence, hypotonia and vomiting has been reported in a neonate following the nursing mother's intake of levodropropizin. Symptoms appeared after the feed and resolved spontaneously by suspending breastfeeding for a few feedings. Only occasionally some adverse reactions were of a serious nature. These include some cases of skin reactions (urticaria, pruritus), the case of cardiac arrhythmia, already mentioned above, the case of hypoglycemic coma, as well as some cases of allergic / anaphylactoid reactions involving edema, dyspnoea, vomiting, diarrhea. As already mentioned, a single case of epidermolysis, which occurred abroad in a polytreated elderly patient, had a fatal outcome. The medicine contains methyl para-hydroxybenzoate, which is known to cause hives. In general, para-hydroxybenzoates can cause delayed reactions, such as contact dermatitis and rarely immediate reactions with manifestation of urticaria and bronchospasm.

Pregnancy and breastfeeding

Studies of teratogenesis, reproduction and fertility as well as peri and postnatal studies did not reveal specific toxic effects. However, since a slight delay in weight gain and growth was observed in animal toxicology studies at a dose of 24 mg / kg and since levodropropizin is able to overcome the placental barrier in the rat, the use of the drug it is contraindicated in women who intend to become or are already pregnant as its safety of use is not documented. Studies in rats indicate that the drug is found in breast milk for up to 8 hours after administration. Therefore the use of the drug during breastfeeding is contraindicated.

Special warnings

The observation that the pharmacokinetic profiles of levodropropizin are not markedly altered in the elderly suggests that dose adjustments or modification of the dosing intervals may not be required in the elderly. However, in light of the evidence that sensitivity to various drugs is impaired in the elderly, special caution should be used when levodropropizin is administered to elderly patients. The effect of administering the product to children under 24 months has not been fully studied and in any case the drug should be used with caution in patients of this age. Caution is advised in patients with severe renal insufficiency (creatinine clearance below 35 ml / min). It is advisable to use caution even in case of simultaneous intake of sedative drugs in particularly sensitive individuals.

The drug contains methyl para-hydroxybenzoate and propyl para-hydroxybenzoate. These excipients are known to cause hives. In general, para-hydroxybenzoates can cause delayed reactions, such as contact dermatitis and rarely immediate reactions with manifestation of urticaria and bronchospasm. Antitussive drugs are symptomatic and should only be used pending diagnosis of the underlying cause and / or therapy effect of the underlying disease. In the absence of information on the effect of food intake on drug absorption, it is advisable to take the drug between meals.

This medicine contains 4 g of sucrose per dose (10 ml): patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase isomaltase insufficiency, should not take this medicine. To be taken into consideration for administration to subjects with diabetes mellitus. The medicine contains methyl para-hydroxybenzoate and propyl para-hydroxybenzoate, which are known to cause hives. In general, para-hydroxybenzoates can cause delayed reactions, such as contact dermatitis and rarely immediate reactions with manifestation of urticaria and bronchospasm. Antitussive drugs are symptomatic and should only be used pending diagnosis of the underlying cause and / or therapy effect of the underlying disease.

The drug does not contain gluten; therefore it can be administered to patients with celiac disease.

Expiry and retention

Check the expiration date indicated on the package. The expiry date indicated on the package refers to the product in intact packaging, correctly stored. The shelf life after first opening the bottle is 6 weeks. The medicinal product should be stored at a temperature not exceeding 25 ° C.

Warning : do not use the medicine after the expiry date indicated on the package.

Composition

100 ml of Levodropropizina Eg Syrup contain:

Active principle

Levodropropizin 600 mg

Excipients

Sucrose, methyl-para-hydroxybenzoate, propyl-para-hydroxybenzoate, citric acid monohydrate, sodium hydroxide, cherry flavor, purified water.

The transport of medicines sold online is carried out in compliance with the guidelines on good distribution practice according to Article 112-quater, paragraph 10. (Italy)