

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tussistop

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml Syrup contains 30 mg Levodropropizine

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL INFORMATION

4.1 Therapeutic Indications

Symptomatic treatment of cough

4.2 Posology and method of administration

Syrup:

A measuring dispenser is attached to the pack.

Adults: 10 ml of syrup up to 3 times daily at intervals of at least 6 hours unless otherwise prescribed by the physician.

Children: 10-20 kg: 3 ml of syrup 3 times a day; 20-30 kg:

5 ml of syrup 3 times a day.

Pediatric population

Do not administer to children under 2 years of age

4.3 Contraindications

Hypersensitivity to the active ingredient or to any of the excipients listed in section 6.1. Administration of the drug should be avoided in patients with bronchial hyper-secretion and with reduced mucosal function (Kartagener syndrome, ciliary dyskinesia).

Pregnancy and Lactation

Do not administer to children under 2 years of age.

4.4 Special warnings and precautions for use

The observation that the pharmacokinetic profiles of Levodropropizine are not significantly altered in the elderly suggests that dosage adjustments or dosage interval changes may not be required in the elderly. In any case, in the light of the evidence that in the elderly, sensitivity to various drugs is altered, special caution should be used when Levodropropizine is administered to elderly patients.

Caution should be taken in patients with severe renal impairment (creatinine clearance below 35 ml / min).

Antitussive drugs are symptomatic and should be used only depending on the diagnosis of the triggering cause and / or the effect of the underlying pathology therapy.

In the absence of information on the effect of food on the absorption of the drug, it is advisable to take the drug apart from meals.

TUSSISTOP syrup does not affect low-calorie and controlled diets, and also can be administered to diabetic patients.

TUSSISTOP syrup contains methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate.

TUSSISTOP solution contains methyl-p-hydroxybenzoate, which can cause allergic reactions (even delayed).

4.5 Interaction with other medicinal products and other forms of interaction

In human pharmacology studies, the association with benzodiazepine does not modify the EEG framework.

However, if necessary caution should be taken in case of simultaneous intake of sedative drugs in particularly sensitive individuals.

There is no interaction with drugs used in the treatment of bronchopulmonary diseases such as beta-2 agonists, methylxanthines and derivatives, corticosteroids, antibiotics, mucous regulators and antihistamines.

4.6 Fertility, pregnancy and lactation

Teratogenesis, reproduction and fertility studies as well as peri-and post-natal studies have revealed no specific toxic effects.

The use of the drug should be avoided in women who intend to become pregnant or are already pregnant as its safe use is not documented. Therefore, the use of the drug during lactation is contraindicated.

4.7 Effects on ability to drive and use machinery

No studies on the ability to drive and / or use machinery have been performed.

However, as the product may, although rarely, cause drowsiness, use with caution in those patients who intend to drive or operate machinery, informing them of this possibility.

4.8 SIDE EFFECTS

Palpitations, tachycardia, nausea, vomiting, diarrhea, erythema may occur during treatment with levodropropizine. The reactions reported as serious are hives and anaphylactic reaction.

Most adverse reactions occurring after levodropropizine intake are not severe and the symptoms have resolved by discontinuation of therapy and, in some cases, with specific pharmacological treatment.

The adverse reactions found (unknown) are as follows:

syrup TUSSISTOP

Levodropropizine 30 mg/5ml



Eye disorders

Mydriasis, bilateral blindness

Immune system disorders

Allergic reactions and anaphylactoid, eyelid edema, angioneurotic edema, urticaria.

Psychiatric disorders

Nervousness, drowsiness, personality alteration, or personality disorder.

Nervous system disorders

Syncope, dizziness, vertigo, tremors, paresthesia, tonic-clonic seizure and petit mal attack, hypoglycemic coma.

Cardiac disorders

Palpitations, tachycardia, atrial bigeminy.

Vascular disorders

Hypotension.

Respiratory, thoracic and mediastinal disorders

Discomfort, cough, respiratory tract edema.

Gastrointestinal disorders

Gastric pain, abdominal pain, nausea, vomiting, diarrhea, glossitis and aphthous stomatitis.

Hepatobiliary disorders

Cholestatic hepatitis.

Skin and subcutaneous tissue disorders

Hives, erythema, exanthema, itching, angioedema, skin reactions. Epidermolysis

Musculoskeletal and connective tissue disorders

Weakness of the lower limbs.

Systemic pathologies and conditions at the site of administration

General malaise, generalized edema, asthenia.

Pediatric population

A case of drowsiness, hypotonia and vomiting has been reported in a newborn baby after taking levodropropizine by the lactating mother. The symptoms appeared after the lactation and spontaneously resolved by suspending the lactation for some feedings.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor or you can report directly via The Egyptian Pharmacovigilance Center:

Telephone: +202 23648046/ 23640368/ 23684381

E-mail: Pv.center@eda.mohealth.gov.eg

By reporting side effects, you can help provide more information on the safety of this medicine

4.9 Overdose

No significant side effects were reported after drug administration up to 240 mg single dose and up to 120 mg t.i.d. For 8 consecutive days. There are known cases of overdose in children of 2 to 4 years of age. These are cases of accidental overdose all resolved without consequences.

In most cases, patients had abdominal pain and vomiting, and in one case, after taking 600 mg of levodropropizine, the patient showed excessive sleep and decreased oxygen saturation. In case of overdose with obvious clinical manifestations, immediately institute symptomatic therapy and apply emergency relief measures (gastric lavage, activated carbon intake, parenteral liquid administration, etc.), as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: cough preparations and Colds:

Other cough sedatives, ATC code: R05DB27

Levodropropizine is a medication with antitussive activity, predominantly peripheral type tracheobronchial, associated with anti-allergic and anti-bronchospasm activity; In addition, it shows a local anesthetic action.

Levodropropizine does not cause depression of respiratory function nor appreciable cardiovascular effects, also does not induce constipating effects in animals.

Levodropropizine acts on the bronchopulmonary system by inhibiting hapten-induced bronchospasm, serotonin and bradykinin. The drug does not inhibit acetylcholine-induced bronchospasm, thus demonstrating the absence of anticholinergic effects.

At therapeutic doses, Levodropropizine does not alter the EEG tracing and psychomotor capacity in humans.

This drug does not depress respiratory function or mucosal clearance in humans.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have been conducted in rat, dog and man.

Absorption, distribution, metabolism and excretion were very similar in the three species considered, with a bioavailability per oral route greater than 75%. Recovery of radioactivity after oral administration of the product was 93%.

The binding to human plasma proteins is negligible (11-14%) and is comparable to that observed in dogs and rats.

syrup TUSSISTOP

Levodropropizine 30 mg/5ml



Levodropropizine is rapidly absorbed in humans after oral administration and is rapidly distributed in the body. The half-life is about 1-2 hours. The product is mainly excreted in urine as an unaltered product and its metabolites (conjugated levodropropizine and p-hydroxy levodropropizine free and conjugated). In 48 hours, the urinary excretion of the product and the above metabolites is approximately 35% of the administered dose. Repeated dose trials demonstrate that a 8-day treatment (t.i.d.) does not alter the absorption and elimination profile of the drug, thus allowing exclusion of metabolic accumulation and metastases. There are no significant changes in the pharmacokinetic profile in children, in the elderly, and in patients with mild to moderate renal impairment.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Glycerin, sorbitol 70% solution, methyl paraben sodium, propyl paraben sodium, citric acid, sucrose, cherry flavor, carmoisine red and purified water

6.2 Special precautions for storage

Store at temperature not exceeding 30°C,
keep out of reach of children.

6.3 Nature and contents of the Pack

Carton box containing amber glass (type III) bottle containing 60 or 100 ml solution with outer label and (HDPE) plastic cap + (PP) measuring cup and an inner leaflet.

7. Manufacturer

ATCO PHARMA FOR PHARMACEUTICAL INDUSTRIES

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