SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DROPOLEV-S 30 mg/5 ml syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):

Levodropropizine	6 mg/ml

Excipient(s):

Sugar	233 mg/ml
Methyl paraben	0.8 mg/ml
Propyl paraben	0.3 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

Colorless to slightly yellow, clear solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

It is indicated for the symptomatic treatment of dry cough (nonproductive cough) due to various causes.

4.2. Posology and method of administration

Posology/frequency of administration and duration of the treatment:

Adults:

Apply 10 ml syrup (2 spoons) three times a day with an interval of at least 6 hours.

Children:

It is used in children older than 2 years.

It is divided into 3 equal doses and administered 3-6 mg/kg per day depending on the severity of the symptoms with an interval of at least 6 hours.

- 3 ml three times per day in patients weighing 10-20 kg (up to the 3 ml mark on the spoon)
- 5 ml (one full spoon) three times per day in patients between 20-30 kg
- 10 ml (two full spoons) three times per day in patients over 30 kg

The drug should be taken until the cough disappears or according to the advice of a physician provided that maximum 7-day treatment period is not exceeded. If the symptoms do not disappear within this period, the drug should be temporarily discontinued, and a physician should be consulted.

Method of administration:

For oral use only.

Although any information that there is effect on the absorption when the drug is taken with food is not available, it is advisable to take the drug a time before or after the meal.

It can be used with a measuring spoon.

Additional information for special populations:

Renal/Hepatic failure: It should be used with caution considering the benefit-risk ratio in cases of the severe renal failure.

Pediatric population: DROPOLEV-S should be administered in pediatric patients as indicated in the posology section. It should not be used in children under 2 years of age.

Geriatric population: The dose of DROPOLEV-S should be determined with caution in elderly patients.

4.3. Contraindications

The drug is contraindicated in cases of known or suspected hypersensitivity to the drug, during pregnancy and lactation, in patients with severe hepatic impairment, in patients with reduced mucociliary clearance mechanisms such as Kartagener's syndrome or ciliary dyskinesia.

4.4. Special warnings and precautions for use

It should be used with caution considering the benefit-risk ratio in cases of the severe renal failure.

Cough medicines provide symptomatic treatment and should be used until the underlying pathology has been treated and/or the triggering cause has been identified.

Since 10 ml of syrup contains 2.3 g of sugar, patients with rare hereditary fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase deficiency should not use this medicine.

This medicinal product contains methyl paraben and propyl paraben and may cause allergic reactions (possibly delayed).

4.5. Interaction with other medicinal products and other forms of interaction

Although no interaction with benzodiazepines has been observed during clinical trials, caution should be exercised, especially in sensitive patients taking sedative medication.

4.6. Fertility, pregnancy and lactation
General advise.

Pregnancy category: D.

Women of childbearing potential/Birth control (contraception)

Levodropropizine has harmful pharmacological effects on pregnancy and/or the fetus/newborn. Therefore, women of childbearing potential should not use this medicine and should use effective contraception.

Pregnancy

Levodropropizine crosses the placental barrier. In humans it has been shown to have a harmful effect on the fetus, therefore it should not be used in pregnant women.

Breast-feeding

Levodropropizine passes into breast milk. It should therefore not be used in breastfeeding mothers.

Reproductive ability/Fertility

In addition to peri-natal and post-natal studies, no specific toxic effects were observed in fertility studies.

4.7. Effects on ability to drive and use machines.

Although there are no studies on driving and using machines, extreme caution should be exercised when driving and using machines as it may cause drowsiness (see section 4.8.).

4.8. Undesirable effects

Adverse reactions considered to be drug related are listed below:

Frequencies are defined as follows: Very common (≥1/10); common (≥1/100 to <1/10); not common (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (can not be estimated based on available data).

Immune system disorders

Very rare: Hypersensitivity reactions

Nervous system disorders

Very rare: Fatigue-asthenia, weakness, drowsiness, headache, vertigo, tremor, paresthesia

Cardiac disorders

Very rare: Palpitations, tachycardia, hypotension

Respiratory, thoracic, and mediastinal disorders

Very rare: Dyspnea, cough, edema in the respiratory tract

Gastrointestinal disorders

Very rare: Nausea, vomiting, heartburn and stomach pain, dyspepsia, diarrhea. Glossitis and aphthous were reported in two cases.

Psychiatric disorders

Very rare: Nervousness, sleepiness, loss of self

Skin and subcutaneous tissue disorders

Very rare: Allergic skin rashes, urticaria, erythema, exanthema, pruritus, angioedema

4.9. Overdose and treatment.

No serious side effects were observed following administration of a single dose of up to 240 mg or a dose of 120 mg 3 times daily for 8 days.

No cases of overdosage with levodropropizine have been reported. However, in case of a possible overdose, a mild, transient tachycardia may occur. In the case of an overdose, the measures to be taken against poisoning include gastric lavage, administration of activated charcoal, initiation of parenteral fluid therapy. No specific antidote is available.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other cough suppressants

ATC code: R05DB27

Levodropropizine is peripheric type that the antitussive effect in the trancheobronchial level.

It has an inhibitory impact on the C fibers and inhibits neuropeptide secretion.

5.2. Pharmacokinetic properties

General characteristics

Absorption: Bioavailability after oral administration was found to be higher than 75%. Binding to plasma proteins is low (11-14%).

Distribution: Levodropropizine is rapidly absorbed and rapidly distributed throughout the body after oral administration in humans.

Biotransformation: There are no data that levodropropizine is significantly metabolized in the liver or other body areas.

Elimination: The plasma elimination half-life of levodropropizine is approximately 1-2 hours. It is primarily excreted in the urine. The active substance is excreted as both unchanged and conjugated or free levodropropizine and conjugated p-hydroxy levodropropizine metabolites. Urinary excretion of this substance and its metabolites within 48 hours is about 35% of the administered dose. The results of the repeated dose studies showed that an 8-day treatment (3 doses per day) does not alter the characteristics of the drug excretion thus, allowing to exclude accumulation or metabolic autoinduction in the body.

5.3. Preclinical safety data

Oral acute toxicity is 886.5 mg/kg, 1287 mg/kg and 2492 mg/kg in rats, mice and guinea pigs, respectively. The therapeutic index in guinea pigs was calculated as the LD_{50}/ED_{50} ratio and ranged from 16-53 after oral administration, depending on the experimental model of cough induction. Toxicity tests following repeated oral administration revealed that 24 mg/kg/day was a non-toxic dose.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sugar

Methyl paraben

Propyl paraben

Ethyl alcohol 96%

Glycerin

Citric acid monohydrate

Cherry flavor

Deionized water

6.2. Incompatibilities

There are no known incompatibilities.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store below 25 °C at room temperature, protected from light.

6.5. Nature and contents of container

It is presented in a 150 ml Type III glass bottle in a cardboard box with a 5 ml spoon marked up to 3 ml and Patient Information Leaflet.

7. MARKETING AUTHORISATION HOLDER

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Türkiye

0 216 456 65 70 (Pbx)

0 216 456 65 79 (Fax)

info@berko.com.tr

8. MARKETING AUTHORISATION NUMBER(S)

2022/529

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16.09.2022

Date of latest renewal:

10. DATE OF REVISION OF THE TEXT