

PATIENT INFORMATION LEAFLET

DROPOLEV-S 30 mg/5 ml Syrup

For oral use.

- **Active substance(s):** 5 ml contains 30 mg levodropropizine (Each ml contains 6 mg levodropropizine).
- **Excipient(s):** Sugar, methyl paraben, propyl paraben, ethyl alcohol 96%, glycerin, citric acid monohydrate, cherry flavor, and deionized water

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. *What DROPOLEV-S is and what it is used for?*
2. *What you need to know before you use DROPOLEV-S?*
3. *How to use DROPOLEV-S?*
4. *Possible side effects*
5. *How to store DROPOLEV-S?*

1. What DROPOLEV-S is and what it is used for?

- DROPOLEV-S is a colorless to slightly yellow, clear solution in a 150 ml glass bottle with a 5 ml spoon.
- DROPOLEV-S contains levodropropizine as an active substance.
- It is used to relieve dry cough (cough without phlegm) due to various causes.

2. What you need to know before you use DROPOLEV-S?

DO NOT use DROPOLEV-S

If;

- You are allergic to levodropropizine or to the components of DROPOLEV-S,
- You are pregnant or breastfeeding,
- You have severe liver impairment,
- You have certain diseases in which it is difficult to expectorate sputum (Kartegener's syndrome and other mucociliary dysfunction diseases, etc.)

Warnings and precautions

- Do not use DROPOLEV-S without consulting your doctor if you have serious kidney failure.
- Do not use DROPOLEV-S without consulting your doctor if you have diabetes.

Cough medicines should be used until the underlying disease has been treated and/or the cough trigger has been identified.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

DROPOLEV-S with food and drink

Although there is no information that taking DROPOLEV-S with food has any effect on absorption, it is recommended to take the medicine some time before or after meals.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

DROPOLEV-S can harm your baby because it crosses the placental barrier, therefore do not use during pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

DROPOLEV-S passes into breast milk, therefore, do not use while breastfeeding.

Driving and using machines

You should be very careful when driving or using machines as it can cause drowsiness.

Important informations about some of the excipients of DROPOLEV-S

This medicinal product contains 0.233 grams/ml sugar. If you have been previously told by your doctor that you are intolerant to certain sugars, please contact your doctor before taking this medicinal product.

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

Other medicines and DROPOLEV-S

Although no interaction between benzodiazepines (sedative sleeping medicines) and levodropropizine has been observed during clinical studies, caution should be exercised when using levodropropizine, especially in sensitive patients taking sedative medicines.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use DROPOLEV-S?

Instructions for use and dosage/frequency of administration:

Use at the doses indicated unless otherwise recommended by your doctor.

DROPOLEV-S is administered as 10 ml (60 mg) syrup (2 spoons) 3 times a day at least 6 hours apart.

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

Route of administration and method:

Although there is no information that taking DROPOLEV-S with food has any effect on absorption, it is recommended to take the medicine some time before or after meals.

DROPOLEV-S is for oral use only.

The syrup is drunk using a spoon.

Different age groups:**Use in 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.

Use in elderly:

The dose of DROPOLEV-S should be carefully determined in elderly patients.

Special cases of use:**Renal/Hepatic failure:**

It should be used in cases of severe renal failure, taking into account the benefit-risk ratio.

If you have impression that the effect DROPOLEV-S is very strong or weak, tell a doctor or pharmacist.

If you use more DROPOLEV-S than you should

If you use more DROPOLEV-S than you should, tell your doctor or pharmacist.

If you forget to use DROPOLEV-S

Do not take a double dose to make up for a forgotten dose.

If you stop using DROPOLEV-S

None.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the followings stop taking DROPOLEV-S and IMMEDIATELY inform your doctor or go to the nearest emergency department

- Difficulty breathing, swelling of the face, lips, tongue or throat, sudden decrease in blood pressure, generalized and severe redness, itching, urticaria (hives)

These are all very serious side effects.

If you have any of these, you are allergic to DROPOLEV-S.

You may need urgent medical attention or hospitalization.

All of these very serious side effects are rare.

If you notice any of the followings immediately inform your doctor or go to the nearest emergency department:

- Nausea and vomiting
- Indigestion
- Burning sensation in the stomach
- Diarrhea
- Inflammation of the tongue, mouth sores
- Weakness, fatigue, drowsiness
- Tremor
- Headache
- Dizziness
- Palpitations
- Heartbeat acceleration
- Irritability, drowsiness, loss of self

These are all serious side effects. You may need urgent medical attention. All of these serious side effects are very rare.

If you experience any one of the followings tell your doctor

- Allergic skin reactions (redness, itching)

These are mild side effects of DROPOLEV-S.

This side effect disappears when the dose is reduced, or treatment is stopped.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store DROPOLEV-S?

Keep this medicine out of the sight and reach of children in its original packaging.

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

Use in accordance with expiry date.

Do not use DROPOLEV-S after the expiry date which is stated on the package.

Do not use DROPOLEV-S if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined

Marketing Authorization 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

Manufacturer:

Pharma Plant İlaç San. ve Tic. A.Ş.

Koşuyolu Mah. Vakıf Sok. No: 4 Kadıköy/İstanbul-Türkiye

0 216 545 20 22 (Pbx)

0 216 545 20 23 (Fax)

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