

## PATIENT INFORMATION LEAFLET

### **DROPOLEV Syrup**

**For oral use.**

**Active substance(s):** Each 5 ml (1 measuring spoon) syrup contains 30 mg levodropropizine and 2 mg chlorpheniramine maleate.

**Excipient(s):** Sucrose, methyl paraben sodium, propyl paraben sodium, citric acid monohydrate, vanilla flavor, raspberry flavor, ponso 4R 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 SYRUP** is and what it is used for?*
- 2- *Before you use **DROPOLEV SYRUP***
- 3- *How to use **DROPOLEV SYRUP**?*
- 4- *Possible side effects?*
- 5- *How to store **DROPOLEV SYRUP***

#### **1 – What DROPOLEV SYRUP is and what it is used for?**

DROPOLEV SYRUP is presented in a bottle of 150 ml with a measuring spoon of 5 ml and a pipette.

DROPOLEV SYRUP contains levodropropizine and chlorpheniramine maleate as active substances.

It is used to relieve dry cough (a cough without phlegm) due to various causes.

#### **2 – Before you use DROPOLEV SYRUP**

**Do not use DROPOLEV SYRUP in the following conditions**

If;

- You are allergic (hypersensitive) to active substances or any of the other ingredients of DROPOLEV SYRUP,
- You are pregnant or you are breast-feeding,
- You have a severe liver disease,
- You have a disease that makes it difficult to remove phlegm (e.g. kartagener's syndrome and mucociliary function disorder),
- If you have taken monoamine oxidase inhibitor (MAOI) e.g. isocarboxazid, linezolid, phenelzine, tranylcypromine and drugs taken for treatment of depression such as tricyclic antidepressants within the last 14 days, do not use DROPOLEV SYRUP.

- It should not be used in children under 6 years.

## **TAKE SPECIAL CARE WITH DROPOLEV SYRUP in the following conditions**

If;

- You have severe kidney failure (creatinine clearance  $\leq$  35 mL/min.),
- You have diabetes
- You have allergy,
- You have gastric ulcer,
- You have heart rhythm disorder,
- You have epilepsy,
- You have increased blood pressure or cardiovascular diseases,
- You have prostate enlargement,
- You have liver failure,
- You have high eye pressure,
- You have bronchitis, bronchiectasis (bronchial dilatation), asthma,
- You have overactive thyroid dysfunction,
- You are over 65 years old, do not use DROPOLEV SYRUP without consulting your doctor.

Cough medicines should not be taken until the treatment of the underlying disease is provided and/or precipitating cause is detected.

“Please consult your doctor, even if these statements were applicable to you at any time in the past.”

### **Using DROPOLEV SYRUP with food and drink**

It is recommended to take it a time before or after meal although there is no data on the effect of DROPOLEV SYRUP taken with food on the absorption. It should not be used with alcohol.

### **Pregnancy**

*Ask your doctor or pharmacist for advice before taking the medicine.*

DROPOLEV SYRUP can harm your baby because it passes across the placental barrier. Therefore, do not use DROPOLEV SYRUP during pregnancy.

*If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Ask your doctor or pharmacist for advice before taking the medicine.*

DROPOLEV SYRUP passes into breast milk. Therefore, do not use DROPOLEV SYRUP during breast-feeding.

### **Effects on ability to drive and use machines**

You should be very careful when driving and using machine, as it may cause drowsiness.

### **Important information about some of the ingredients of DROPOLEV SYRUP**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

DROPOLEV SYRUP contains methyl paraben sodium and propyl paraben sodium which may cause allergic reactions (possibly delayed).

This medicinal product contains less than 1 mmol (23 mg) of sodium per each 5 ml, i.e. essentially 'sodium-free'.

DROPOLEV SYRUP contains ponso 4R which may cause allergic reactions.

### **Using with other medicines**

Caution should be taken in susceptible patients taking sedative medicines such as alprazolam, bromezapam, diazepam, clonazepam, clorazepate, chlordiazepoxide, buspirone, hydroxyzine, zolpidem

*Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.*

### **3 – How to use DROPOLEV SYRUP**

#### **Instructions for appropriate method and dose/frequency of administration:**

Take specified dosage unless recommended otherwise by your doctor.

DROPOLEV SYRUP is administered as 10 ml syrup (2 measuring spoons) three times a day with an interval of at least 6 hours in adults.

The drug should be taken until the cough disappears or according to the advice of a doctor provided that maximum 7-day treatment period is not exceeded. If the symptoms do not disappear within this period, the medication should be temporarily discontinued and a doctor should be consulted. Cough is a symptom of disease and therefore, the cause of the actual disease should be investigated and treated

#### **Route and method of administration:**

It is recommended to take it a time before or after meal although there is no data on the effect of DROPOLEV SYRUP taken with food on the absorption.

DROPOLEV SYRUP is only for oral use.

Drink syrup using a measuring spoon or pipette.

#### **Different age groups:**

##### **Use in children:**

Use for children over 6 years.

Apply 3-6 mg/kg/day divided into three equal doses with an interval of at least 6 hours based on the severity of symptoms.

3 ml three times per day in children weighing 10-20 kg (3 ml using pipette)

5 ml three times per day in children weighing 20-30 kg (one full spoon)

10 ml three times per day in children over 30 kg (two full spoons)

It is not recommended to use in children between the ages of 6-12.

##### **Use in elderly:**

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

##### **Special populations:**

##### **Kidney/Liver failure:**

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

*If you have the impression that the effect of DROPOLEV SYRUP is too strong or too weak, talk to your doctor or pharmacist.*

**If you have used more DROPOLEV SYRUP than you should:**

*If you may have taken more DROPOLEV SYRUP than you should, talk to a doctor or pharmacist.*

**If you forget to use DROPOLEV SYRUP**

*Do not use a double dose to make up for a forgotten dose.*

**If you stop taking DROPOLEV SYRUP**

Not applicable.

**4 - Possible side effects?**

Like all medicines, side effects can occur in people sensitive to the contents of DROPOLEV SYRUP.

**If any of the following occur stop using DROPOLEV SYRUP and IMMEDIATELY inform your doctor or go to the nearest emergency department:**

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

These are all very serious side effects.

If you have any of them, this means you have serious allergy to DROPOLEV SYRUP. You may need emergency medical care or hospitalization.

Side effects are classified as follows:

Very common: may be seen at least 1 in 10 patients

Common: may be seen less than one in 10 patients but more than one in 100 patients

Uncommon: may be seen less than one in 100 patients but more than one in 1000 patients

Rare: may be seen less than one in 1000 patients but more than one in 10.000 patients

Very rare: may be seen less than one in 10000 patients

Unknown: cannot be estimated from the available data

**Very common** (may be seen at least 1 in 10 patients)

- Sedation (allayment),
- Somnolence.

**Common** (may be seen less than one in 10 patients but more than one in 100 patients)

- Exhaustion,
- Constipation,
- Vomiting,
- Dry mouth,
- Attention deficit,
- Abnormal coordination,
- Dizziness.

**Rare** (may be seen less than one in 1000 patients but more than one in 10.000 patients)

- Urinary retention.

**Very rare** (may be seen less than one in 10000 patients)

- Hypersensitivity reaction,
- Fatigue-asthenia, weakness,
- Lethargy,
- Headache,
- Dizziness due to impaired balance (Vertigo),
- Tremor,
- Feeling of numbness (Paresthesia),
- Palpitation,
- Low blood pressure (Hypotension),
- Shortness of breath (Dyspnea),
- Cough,
- Edema in the respiratory tract,
- Nausea, heartburn and pain,
- Dyspepsia,
- Diarrhea,
- Nervousness,
- Drowsiness, loss of self,
- Skin redness (Erythema),
- Skin rash (exanthema),
- Skin reactions where soft tissue in hands and feet, lips, genital organs and eyelids have deeper and wider edema (angioedema)
- Weakness in legs,
- Temporary visual loss and enlargement of pupils,
- Sara-like seizure (epilepsy).

**Unknown** (it cannot be estimated from the available data)

- Severe allergic reactions (Anaphylactic reactions),
- Darkening of bronchial secretions,
- Insomnia,
- Increased excitability,
- Anxiety,
- Clouding of consciousness (Confusion),
- Anger easily (Irritability),
- Nightmares,
- Depression,
- Common redness and peeling of the skin (Exfoliative dermatitis),
- Redness,
- Sensitivity to light (photosensitivity),
- Hemolytic anemia,
- Blood disorders (Blood dyscrasias),
- Loss of appetite (Anorexia),
- Blurred vision,
- Tinnitus,
- Hepatitis, jaundice,
- Muscle twitching and muscle weakness,

- Chest pain and tightness,
- Irregular heartbeat (arrhythmia).

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

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website [www.titck.gov.tr](http://www.titck.gov.tr) or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine

#### **5 – How to store DROPOLEV SYRUP**

*Keep in the original package and out of the reach and sight of children.*

Store in room temperature under 25°C protecting from light.

#### **Use in accordance with expiry date.**

*Do not use DROPOLEV SYRUP after the expiry date which is stated on the packaging.*

Do not use DROPOLEV SYRUP if you notice any damage on the product and/or packaging.

#### ***Marketing Authorization Holder:***

Berko İlaç ve Kimya San. A.Ş.

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

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

[info@berko.com.tr](mailto:info@berko.com.tr)

#### ***Manufacturer:***

Berko İlaç ve Kimya San. A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

*This patient information leaflet was approved on 14/06/2016.*