



## PACKAGE LEAFLET

### **LEDROPIN 30 mg/5 ml Syrup**

**Taken by mouth.**

**Active substance:** Each 5 ml syrup (one measuring spoon) contains 30 mg levodropropizine.

**Excipients:** Methyl paraben, propyl paraben, sucrose, cherry flavor, citric acid monohydrate, sodium hydroxide, purified water

**Read all of this PACKAGE LEAFLET carefully before you start taking 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower dose** other than recommended to you.*

#### **In This Leaflet:**

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

#### **1. WHAT LEDROPIN IS AND WHAT IT IS USED FOR**

LEDROPIN is a colorless, cherry-scented syrup free from visible foreign particle, presented in 150 ml amber colored type III glass bottle with HDPE plastic cap, and with a plastic measuring spoon marked to 3 ml and 5 ml.

LEDROPIN contains levodropropizine as active substance.

LEDROPIN is used relieve dry cough of various causes.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEDROPIN**

**DO NOT take LEDROPIN, if**

- You are allergic to levodropropizine or any of the other ingredients of LEDROPIN,
- You are pregnant or breast-feeding,
- The patient is younger than 2 years of age,
- You have severe liver failure,
- You suffer from certain respiratory disorders characterized by reduced ability to expel mucus (such as Kartagener's syndrome or other mucociliary dysfunction diseases)

#### **TAKE SPECIAL CARE with LEDROPIN**

Do not take LEDROPIN before consulting you doctor, if:

- You have severe kidney problems
- You have diabetes



- You are older than 65 years of age
- The patient is under 6 years of age

LEDROPIN should not be used for long-term treatments.

Cough medicines should be used until the underlying disease is treated and/or until the triggering cause of the cough is determined.

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

### **Taking LEDROPIN with food and drink**

Although there is no information that taking LEDROPIN with food has any effect on absorption, it is recommended to take the medicine a while before or after meals.

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine.*

As levodropropizine is able to cross the placental barrier it may harm your baby, and therefore do not use it during pregnancy.

*If you realize you are pregnant during your treatment, immediately consult your doctor or pharmacist.*

### **Breast-feeding**

*Consult your doctor or pharmacist before taking this medicine.*

As levodropropizine passes into breast-milk, do not use it while breast-feeding.

### **Driving and using machines**

This medicine may cause drowsiness, so take special care while driving or using machines.

### **Important information about some of the ingredients of LEDROPIN**

LEDROPIN contains 2.612 g sucrose per one measuring spoon (5 ml). This should be taken into account in patients with diabetes mellitus.

LEDROPIN contains 10.98 mg sodium per one measuring spoon (5 ml). This should be taken into account for patients on a controlled sodium diet.

LEDROPIN contains methyl paraben and propyl paraben, which may cause allergic reactions (possibly delayed).

### **Taking other medicines**

Although no interaction between benzodiazepines (sedative sleep medications) and levodropropizine has been observed during clinical trials, care should be taken in case of the concomitant intake of sedative (soothing) drugs in particularly sensitive patients.

*Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.*

## **3. HOW TO TAKE LEDROPIN**

### **Instructions for proper use and dose/administration frequency:**

Always take this medicine in the doses given below, unless otherwise recommended by your doctor.



The recommended dose for adults is 10 ml of syrup (60 mg) (2 measuring spoons) 3 times a day. Leave at least 6 hours between the doses.

The medicine should be taken until the cough disappears or on the advice of a doctor, not exceeding the maximum 7-day treatment period. If the symptoms do not disappear within this period, stop taking this medicine temporarily and seek medical advice.

**Route and method of administration:**

Due to the lack of information on the influence of meals on the absorption of LEDROPIN, it is recommended to take it a while before or after meals.

LEDROPIN is for oral use only.

Take the syrup with the measuring cup provided with the medicine.

**Different age groups:**

**Use in children:**

It is administered as 3-6 mg per kilogram per day, divided into 3 equal doses with at least 6 hour intervals, depending on the severity of the illness.

For children weighing 10-20 kg: 3 ml (up to 3 ml line on the measuring spoon) 3 times per day.

For children weighing 20-30 kg: 5 ml (one measuring spoon) 3 times per day.

For children over 30 kg: 10 ml (two measuring spoons) 3 times per day.

**Use in the elderly:**

The dose of LEDROPIN should be carefully determined in elderly patients.

**Use in special conditions:**

**Kidney/Liver failure:**

In cases of severe kidney failure, it should be used considering the benefit-risk ratio.

*If you think that the effect of LEDROPIN is too strong or too weak, talk to your doctor or pharmacist.*

**If you take more LEDROPIN than you should:**

*If you take more LEDROPIN than you should, consult your doctor or pharmacist.*

**If you forget to take LEDROPIN:**

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

**Effects that may occur when treatment with LEDROPIN is terminated:**

None.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, side effects may occur in people with sensitivity to ingredients of LEDROPIN.

**If any of the following side effects happens, stop taking LEDROPIN, and contact your doctor or go to your nearest hospital emergency room IMMEDIATELY:**



Difficulty breathing, swelling of face, lips, tongue or throat, sudden drop in blood pressure, widespread and severe redness, pruritus, urticaria (hives)

These are all very serious side effects.

If you have any of these, you are severely allergic to LEDROPIN. You may need emergency medical intervention or hospitalization.

All of these very serious side effects are very rare.

**If you notice any of the following, notify your doctor immediately or contact the emergency department of your nearest hospital:**

- Nausea - Vomiting
- Indigestion
- Heartburn
- Diarrhea
- Inflammation of the tongue, mouth ulcers
- Weakness – Fatigue - Drowsiness
- Tremors
- Headache
- Dizziness
- Palpitations
- Rapid heartbeat
- Irritability, drowsiness, depersonalization

These are all serious side effects. They may require immediate medical attention. Serious side effects are seen very rarely.

**Inform your doctor if you notice any of the following:**

- Allergic skin reactions (redness, itching)

These are mild side effects of LEDROPIN.

They disappear when the dose is decreased or after termination of therapy.

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

#### Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. HOW TO STORE LEDROPIN**

*Keep LEDROPIN out of the reach and sight of children and in its original container.*

Store at room temperature below 30°C, protected from light.

**Take this medicine in accordance with expiry date.**

*Do not use LEDROPIN after the expiry date which is stated on the container.*



Do not use LEDROPIN if you notice any defects on product and/or its package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

***Marketing Authorization Holder:***

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***Manufacturing site:***

DEVA Holding A.Ş.  
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