

PATIENT INFORMATION LEAFLET

PULMOREST® 30 mg/5 ml Syrup **Administered orally.**

- **Active Substance:** Contains 6 mg Levodropropizine in 1 ml.
- **Excipients:** Sucrose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium hydroxide, citric acid monohydrate, cherry flavor and deionized water.

Please read the PATIENT INFORMATION LEAFLET carefully before starting the use of this pharmaceutical, since it contains important information for you.

- *Keep the patient information leaflet. You may need to read it again later.*
- *In case you have additional questions, please consult to your physician or your pharmacist.*
- *This pharmaceutical has been personally prescribed for you; do not give it to other persons.*
- *During the use of this pharmaceutical, tell your physician that you are using this pharmaceutical during your visit to the physician or hospital.*
- *Please comply with the instructions herein. Do not use a dose, **lower or higher** than the recommended dose.*

In this Patient Information Leaflet:

- 1. What is PULMOREST® and what is it used for?**
- 2. Issues prior to the use of PULMOREST®**
- 3. How is PULMOREST® used?**
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Are explained.

1. What is PULMOREST® and what is it used for?

- PULMOREST® is available in 150 and 200 ml amber-colored glass bottles with 10 ml measuring cup. It has a colorless-pale yellow, clear solution appearance.
- PULMOREST® contains levodropropizine as active substance.
- PULMOREST® is used for the suppression of dry cough (unproductive cough), associated with various causes.

2. Issues prior to the use of PULMOREST®

DO NOT USE PULMOREST® in following cases

- If you have allergy against levodropropizine or any ingredients of PULMOREST®
- If your child is under the age of 2
- If you are pregnant or breastfeeding,
- In case you have a severe liver failure,
- If you have difficulty in excreting phlegm.

USE PULMOREST® WITH CAUTION in case of following

If you have severe kidney dysfunction,

If you have diabetes,

If you are over 65 years old

PULMOREST® is not recommended in children under the age of 6

Cough medication must be used until the underlying condition is treated and/or the cause, triggering cough is determined.

In case these warnings apply to you, even if for any period in the past, please consult to your physician.

The use of PULMOREST® with food and beverage

Although there is no information, suggesting that administration of PULMOREST® with food has any effect on absorption, it is recommended to take the drug some time before or after meals.

Pregnancy

Please consult your physician or pharmacist before using the pharmaceutical.

Since PULMOREST® crosses placenta barrier, it may damage your baby and therefore do not use it.

Consult your physician or your pharmacist immediately in case you realize that you are pregnant during treatment.

Lactation

Please consult your physician or pharmacist before using the pharmaceutical.

PULMOREST® is excreted in breast-milk, therefore do not use when lactating.

Driving and Operating Machinery

Since it may cause somnolence, you must be very careful when driving and operating machinery.

Important information concerning some of the excipients, contained in PULMOREST®

PULMOREST® contains sucrose. If you have been told by your physician that you had intolerance to certain sugars, you should contact with your physician before taking this medicinal product.

Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), contained in PULMOREST®Syrup, may cause allergic reactions (possibly delayed).

Use with other pharmaceuticals

Although no interactions between benzodiazepines (sedative sleeping pills) and PULMOREST® have been observed in clinical studies, caution should be exercised when using it in sensitive patients, especially those taking sedative (tranquilizer) medications.

In case you are using or have recently used any prescription or over-the-counter pharmaceuticals please report these to your physician or your pharmacist.

3. How is PULMOREST® used?

Instructions for appropriate usage and dosage/application frequency:

Unless otherwise recommended by the physician, use at specified dosages. PULMOREST® is administered to adults as 10 ml (60 mg) syrup (up to the 10 ml line on the scale) 3 times a day and at least 6 hours apart.

The drug should be taken until the cough disappears or as recommended by a doctor, provided that it does not exceed a maximum of 7 days of treatment. If the symptoms do not disappear within this period, the use of the drug should be temporarily stopped and a doctor should be consulted.

Administration route and method:

Although there is no information, suggesting that administration of PULMOREST® with food has any effect on absorption, it is recommended to take the drug some time before or after meals.

PULMOREST® is only for oral administration.

The syrup is taken using the measuring cup.

Different age groups:

Use in children:

PULMOREST® must not be used in children under the age of 2

PULMOREST® is not recommended in children under the age of 6

Administered at a daily dose of 3-6 mg per kilogram, according to the severity of symptoms, at 6-hour intervals, by dividing into 3 equal doses.

3 ml (up to 3 ml line in the measurement cup) 3 times a day for children between 10 to 20 kg

5 ml (up to 5 ml line in the measurement cup) 3 times a day for children between 20 to 30 kg

10 ml (up to 10 ml line in the measurement cup) 3 times a day for children over 30 kg.

Use in elderly:

PULMOREST® dose must be carefully determined in the elderly.

Special usage conditions:

Kidney/Liver failure:

In case of severe kidney, the dose will be adjusted by your physician

In case you have an impression that the effect of PULMOREST® is too weak or too strong, talk to your physician or your pharmacist.

If you used more PULMOREST® than you should have used

In case you used PULMOREST® at an amount that is more than you were supposed to, talk to a physician or a pharmacist.

If you forget to use PULMOREST®

Do not take double doses to compensate for forgotten doses.

Effects, which may occur on termination of treatment with PULMOREST®

N/A.

4. What are the possible side effects?

Like all pharmaceuticals, side effects can be seen in people that are sensitive to the contents of PULMOREST®.

If any of the following occurs, stop taking PULMOREST® and inform your doctor IMMEDIATELY or refer to the emergency room of the nearest hospital.

Difficulty in breathing, swelling in face, lips, tongue or throat, sudden decrease in blood pressure, widespread and severe flushing, itching, urticaria.

All these are serious side effects.

In case you have one of these, it means that you have a serious allergy to PULMOREST®. You may need emergency medical attention or hospitalization.

All of these serious side effects are seen very rarely.

Very common: Seen in at least 1 of 10 patients.

Common: May be seen in less than one out of 10 patients yet more than one out of 100 patients.

Uncommon: May be seen in less than one out of 100 patients yet more than one out of 1000 patients.

Rare: May be seen in less than one out of 1,000 patients yet more than one out of 10,000 patients.

Very rare: May be seen in less than one out of 10,000 patients.

Unknown: Can not be estimated from available data.

If any of the following occurs, call your doctor IMMEDIATELY and refer to the emergency service of the nearest hospital:

Very rare:

- Nausea-vomiting
- Indigestion
- Burning sensation in stomach
- Diarrhea
- Inflammation of tongue, mouth ulcers
- Fatigue-Tiredness-Numbness
- Tremors
- Headache
- Dizziness
- Palpitation
- Increase in heart rate
- Irritability, somnolence, loss of consciousness

These are serious side effects. Immediate medical response may be required.

Serious side effects are seen very rarely.

In case you observe any side effects, which are not mentioned in this patient information leaflet, please inform your physician or your pharmacist.

Reporting of side effects

In case of a side effect, which is given in the Patient Information Leaflet or not, consult your physician, pharmacist or nurse. In addition, report your side effects to Turkey Pharmacovigilance Center (TÜFAM) by clicking on "Pharmaceutical Side Effect Report" button on www.titck.gov.tr via side effect report line 0 800 314 00 08. By reporting side effects, you will provide a contribution to obtain greater information concerning safety of the pharmaceutical you use.

5. Storage of PULMOREST®

Keep PULMOREST® away from reach and sight of children and in package.
Must be stored below 30°C, in room temperature, away from light.

Use in compliance with expiry date.

Do not use PULMOREST® after the expiry date on the package.

In case you notice irregularities on the product and/or package, do not use PULMOREST®.

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This patient information leaflet has been approved on 11.12.2018.