

PATIENT INFORMATION LEAFLET

PULMOREST FORT 60 mg/5 ml Syrup

Administered orally.

- **Active Substance:** Each ml contains 12 mg levodropropizine
- **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 FORT and what is it used for?**
- 2. Issues prior to the use of PULMORESTFORT**
- 3. How is PULMOREST FORT used?**
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Are explained.

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

- PULMOREST FORT is presented in 100 ml of honey-colored bottles, containing 75ml syrup, packed with 5 ml measuring spoon with 1,5ml, 2,5ml, and 5ml notches. It has a colorless-pale yellow, clear solution appearance.
- PULMOREST FORT contains levodropropizine as active substance.
- PULMOREST FORT is used for the suppression of dry cough (unproductive cough), associated with various causes.

2. Issues prior to the use of PULMOREST FORT

DO NOT USE PULMOREST FORT in following cases

- If you have allergy against levodropropizine or any ingredients of PULMOREST FORT
- If you are pregnant or breastfeeding,
- If your child is under the age of 2
- In case you have a severe liver failure,
- If you have difficulty in excreting phlegm. (Kartagener syndrome and mucociliary dysfunction)

USE PULMOREST FORT WITH CAUTION in case of following

- If you have severe kidney dysfunction, (creatinine clearance < 35 ml/min)
- If you have diabetes
- If you over 65 years of age.

do not use PULMOREST FORT without consulting your physician.

PULMOREST FORT should not be used in long-term treatments

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

If you did not get any progress after short-term treatments, consult to your physician.

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

The use of PULMOREST FORT with food and beverage

Although there is no information, suggesting that administration of PULMOREST FORT 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 FORT 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 FORT 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 FORT

Methyl parahydroxybenzoate and propyl parahydroxybenzoate, contained in PULMOREST FORT, may cause allergic reactions (possibly delayed).

PULMOREST FORT 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.

Use with other pharmaceuticals

Caution must be exercised when used in sensitive patients, taking sedatives like alprazolam, bromezapam, diazepam, clonazepam, clorazepate, chlordiazepoxide, buspirone, hidroxyzine zolpidem.

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 FORT used?

Instructions for appropriate usage and dosage/application frequency:

Unless otherwise recommended by the physician, use at specified dosages.

In adults, PULMOREST FORT is administered at a dose of 5 ml (60 mg) three times a day and with at least 6-hour intervals.

The treatment must be administered until the cough disappears or according to the recommendation of the physician, provided that the treatment does not exceed 7 days. In case the symptoms do not disappear within this term, the use of drug must be interrupted temporarily and a physician must be consulted. Cough is a symptom of illness. Actual disease effect should be investigated and treated.

Administration route and method:

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

PULMOREST FORT is only for oral administration.

The syrup is taken by using the measuring spoon.

Different age groups:

Use in children:

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.

1,5 ml of syrup up to 3 times daily for children between 10 to 20 kg

2,5 ml of syrup up to 3 times daily for children between 20 to 30 kg

5 ml of syrup up to 3 times daily for children over 30 kg.

Use in elderly:

PULMOREST FORT dose must be carefully determined in the elderly.

Special usage conditions:

Kidney/Liver failure:

In case of severe kidney (creatinine clearance < 35 ml/min), it must be used by considering risk-benefit ratio.

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

If you used more PULMOREST FORT than you should have used

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

If you forget to use PULMOREST FORT

Do not take double doses to compensate for forgotten doses.

Effects, which may occur on termination of treatment with PULMOREST FORT
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 FORT.

If any of the following occurs, stop taking PULMOREST FORT 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 FORT. You may need emergency medical attention or hospitalization.

All of these serious side effects are seen very rarely.

The side effects have been described as shown in the following categories:

Very common: These may affect more than 1 in 10 people.

Common: These may affect up to 1 in 10 people, more than 1 in 100 people.

Uncommon: These may affect up to 1 in 100 people, more than 1 in 1.000 people.

Rare: These may affect up to 1 in 1000 people, more than 1 in 10.000 people

Very rare: These may affect up to 1 in 10.000 people,

Unknown: Can not be estimated from available data.

Very rare:

- Hypersensitivity reactions
- Nausea-vomiting
- Indigestion
- Burning sensation in stomach
- Diarrhea
- Inflammation of tongue, mouth ulcers
- Fatigue-Tiredness-Numbness
- Tremors
- Headache
- Dizziness
- Epilepsy(convulsions)
- Palpitation
- Edema in the respiratory tract
- Hypoglycemia
- Irritability, somnolence, loss of consciousness
- Weakness in the legs.
- Temporary loss of vision or enlargement pupilla
- Hypotension
- Cough
- Shortness of breath

- Dyspnea Skin reactions (angioedema) which found deeper and wider edema in soft tissue of hand, feet, lip, genital organs and eyelid

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 FORT

Keep PULMOREST FORT 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 FORT after the expiry date on the package.

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

Do not throw away drugs that have expired or not used! Deliver to the collection system determined by Ministry of Environment and Urbanism.

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This leaflet has been approved on 31/10/2010