

## PATIENT INFORMATION LEAFLET

### **PULMOR 15 mg/5ml pediatric syrup**

**It is used orally.**

- **Active ingredient :** 5 ml syrup solution contains 15 mg ambroxol HCl.
- **Excipients :** Sorbitol 70% solution (E420), benzoic acid, strawberry essence, deionized water

**Please read these LEAFLET carefully before you start using this medicine because it contains important information for you.**

Keep these leaflet. You can need to read again.

If you have other questions, please talk your doctor or pharmacist

This drug has been prescribed for you personally, please do not give it to others.

- If you go to the doctor or hospital during the use of this medicine, tell your doctor that you are taking it.

Follow these leaflet exactly. Do not use high or low doses other than the recommended dose.

### **In these leaflet :**

**1. What is PULMOR and what is it used for?**

**2. Precautions before using PULMOR**

**3. How to use PULMOR**

**4. What are the possible side effects?**

**5. Storage of PULMOR**

**Headlines are included.**

**1. What is PULMOR and what is it used for?**

PULMOR is an expectorant that dilutes the phlegm secretion and facilitates its secretion. In this way, the expulsion of phlegm easily eliminates respiratory distress and reduces cough. PULMOR is supplied in colored glass bottles containing 150 ml syrup, together with a 15 ml scaled cup. Colorless or slightly yellowish clear syrup appearance.

PULMOR is used as an expectorant in sudden and persistent respiratory diseases with the phlegm being dark and sticky.

## **2. Precautions before using PULMOR**

**DO NOT use PULMOR in the following cases.**

If you are hypersensitive to bromhexine or ambroxol.

**USE PULMOR CAREFULLY in the following cases**

Use with extreme caution if you have kidney, liver disease or peptic ulcer (ulcer that develops in the stomach, duodenum or lower pharynx).

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

**Use of PULMOR with food and beverage**

Syrup is taken after meals.

**Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

Since there are not enough clinical studies, it can be used in the first trimester of pregnancy, but only when necessary, by performing benefit-risk assessment.

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

**Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

It should be used very carefully in nursing.

**Vehicle and machine use**

There is no information that PULMOR affects your ability to drive and use machines; caution should be exercised.

### **Important information about certain excipients contained in PULMOR**

PULMOR contains sorbitol (E420). If you have already been told by your doctor that you are vulnerable to certain sugars, contact your doctor before taking this medicinal product.

### **Concomitant use with other drugs**

Do not use together with antitussives such as codeine, which may prevent the expulsion of phlegm. Consider that atropine (a drug used to enlarge the pupil and prevent cardiac arrest, but with a reducing effect on sweat, cough and mucus secretions) and amantadine which shows antimuscarinic effect (a group of drugs that block a substance called acetylcholine in the nervous system), haloperidol (a group of drugs used to treat schizophrenia), antihistamines (a group of drugs used to treat allergies), other drugs (ipratropium- a group of drugs used in lung diseases) like procainamide (a group of drugs used to treat heart rhythm disorder) can cause the accumulation of mucosal fluid. There is no mutual interaction with heart glycosides (a group of drugs used in heart failure), corticosteroids (a group of hormones used in the treatment of pain and inflammation), bronchodilators (drugs that expand the airways called bronchi in the lungs), diuretics (drugs that increase the formation of urine) and antibiotics (drugs acting against microorganisms).

*If you are currently using or taking any prescription or over-the-counter medication, please inform your doctor or pharmacist.*

### **3. How to use PULMOR?**

#### **Instructions for proper use and frequency of dosage / administration:**

In children;

0-2 years: ½ cup (2.5 mL) two times a day

2-5 years: ½ cup (2.5 mL) three times a day

5-12 years: 1 cup 5 mL two or three times a day

At the beginning of treatment, the doses may increase by a factor of one.

Your doctor will tell you how long your treatment with PULMOR will last.

#### **Method of Administration:**

It is taken orally.

**Different age groups:**

**Use in children:** For use in infants and children aged 0-12 years, see section "Instructions for proper use and dosage / administration frequency".

**Elderly use:** There is no specific case for use in elderly patients.

**Special use cases:**

**Kidney / Liver failure:** It should be used with extreme caution in patients with kidney, liver disease and peptic ulcer.

Talk to your doctor or pharmacist if you have the impression that the effect of PULMOR is too strong or too weak.

**If you have used more PULMOR than you should**

So far no cases of poisoning have been reported in humans. In case of overdose, the stomach is emptied and washed, and symptomatic and supportive treatment is applied.

*Talk to a doctor or pharmacist if you have used more than you should use from PULMOR.*

**If you forget to use PULMOR**

*Do not take double doses to compensate for forgotten doses.*

**Effects that may occur when treatment with PULMOR is discontinued:**

It is unknown.

**4. What are the possible side effects?**

Like all medicines, people who are sensitive to the ingredients of PULMOR may have side effects.

**Stop using PULMOR and notify your doctor IMMEDIATELY if any of the following occurs, or contact the emergency department of your nearest hospital:**

- Skin rash
- Change in mucosa
- Swelling on the face
- Difficulty breathing

These are all very serious side effects.

If you have one of these, you have a serious allergy to PULMOR.

You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

Side effects are listed as follows according to their frequency:

Very common : It can be seen in at least one of 10 patients.

Common : Less than one in 10 patients, but more than one in 100 patients.

Not common : Less than one in 100 patients, but more than one in 1,000 patients.

Rarely : Less than one in 1,000 patients may be seen.

Very rare : Less than one in 10,000 patients can be seen.

Unknown : Unable to estimate from the available data.

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

**Uncommon:**

- Allergic reactions (eg skin rash, facial swelling, shortness of breath, itching),
- Fire
- Headache
- Nausea,
- Abdominal pain,
- Vomiting,
- Diarrhea
- Weakness
- Transient elevations in serum aminotransferase levels

**Very rare:**

- Anaphylactic reactions up to shock

*Inform your doctor or pharmacist if you encounter any side effects not mentioned in these instructions for use.*

## **5. Storage of PULMOR**

*Keep PULMOR out of the reach of children and in its packaging.*

Store at room temperature below 25°C.

Use in accordance with expiration dates.

Do not use PULMOR after the expiration date printed on the box.

Do not use PULMOR if you notice defects in the product and / or packaging.

***Marketing Authorization Holder*** : DrogSan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. sok. 7/3

06520 Balgat-ANKARA

***Manufacturing Site*** : DrogSan İlaçları San. ve Tic. A.Ş.

06760 Çubuk-ANKARA

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