

PACKAGE LEAFLET

PULMISTAT[®] 7.5 mg/5 ml Syrup

To be taken orally

- **Active ingredient:** Each 5 ml of syrup contains 7.5 mg of butamirate citrate
- **Excipients:** Sodium saccharine dihydrate, carboxymethyl cellulose sodium, benzoic acid (E210), glycerine, sorbitol (E420), apricot flavor, sodium hydroxide or hydrochloric acid, pure water.

Read all of this 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.*
- *Ask your pharmacist if you need more information or advice.*
- *This medication has been specifically prescribed for you. Do not pass it onto others.*
- *Inform your doctor if you attend a medical facility while taking this medicine.*
- *Follow the instructions stated herein. Do not take **lower or higher** doses than recommended by your doctor.*

What is in this leaflet

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

1. What PULMISTAT[®] is and what it is used for

- PULMISTAT[®] contains the active ingredient butamirate citrate in syrup form.
- PULMISTAT[®] belongs to a group of medicines called anti-tussives.
- PULMISTAT[®] is marketed in 100 ml amber-colored bottles with white plastic pilfer-proof caps, as well as with a measuring spoon. It is a colorless, clear solution.
- PULMISTAT[®] is used for the symptomatic treatment of cough caused by different conditions.

2. What you need to know before you take PULMISTAT[®]

Do not take PULMISTAT[®]

If you and your child are allergic to butamirate or any of the other ingredients of PULMISTAT[®] (see the list of excipient).

PULMISTAT[®] must not be used in children under 3 years of age.

PULMISTAT[®] should be used CAREFULLY in the following conditions:

If you/your child is taking other expectorant medications at the same time with PULMISTAT[®], care should be taken. It is recommended not to take PULMISTAT[®] simultaneously with these medications.

If these apply to you/your child or even if they applied to you in the past, please consult your doctor.

If the cough persists for more than 7 days, please consult with your doctor or pharmacist.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

You should not take PULMISTAT[®] during the first trimester of pregnancy.

You should only take PULMISTAT[®] during the second or third trimester of pregnancy if your doctor thinks that it is absolutely necessary.

If you think you may be pregnant, immediately consult with your doctor or pharmacist.

Breastfeeding

Ask your doctor or pharmacist before taking this medicine.

If you are breastfeeding, ask your doctor before taking PULMISTAT[®].

Driving and using machines

PULMISTAT[®] may cause drowsiness. PULMISTAT[®] should be used with caution if you drive or use machines.

Information on some of the excipients in PULMISTAT[®]

PULMISTAT[®] contains sorbitol as an excipient. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. If you have been prescribed to take 5 ml of PULMISTAT[®] four times daily, PULMISTAT[®] may cause a mild laxative effect due to sorbitol. The caloric value is 2.6 kcal/g sorbitol.

PULMISTAT[®] contains less than 10 g of glycerin in a 5 ml dose. No adverse effects due to glycerin is expected due to its dose.

This medicinal product contains less than 1 mmol (23 mg) of sodium in each dose; in other words, adverse effects due to sodium are unlikely.

Also this product contains benzoic acid. However no unwanted effects are expected due to its route of administration.

Use with other medications

If you are taking other expectorating agents, talk to your doctor.

If you are taking any prescribed/non-prescribed medicines or have taken recently, please inform your doctor or pharmacist.

3. How to take PULMISTAT[®]

Instructions for use and/or frequency of administration:

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you to do so.

Use in children under 6 years of age is not recommended.

Children between 6 and 12 years of age: 2 tablespoons three times daily (10 ml)

Adolescents over 12 years of age: 3 tablespoons three times daily (15 ml)

Adults: 3 tablespoons four times daily (15 ml)

Do not take PULMISTAT[®] for more than 7 days unless prescribed by your doctor.

Route and method of administration:

PULMISTAT[®] is to be taken orally.

Use the enclosed measuring spoon (5 ml) for proper dosing. Clean and dry the measuring spoon after use.

Age groups:

Use in children:

PULMISTAT[®] is not recommended in children under 6 years of age.

Use in the elderly:

Use of PULMISTAT[®] has not been investigated in the elderly.

Special precautions:

Use of PULMISTAT[®] has not been investigated in patients with renal or hepatic insufficiency.

If you have an impression that the effect of PULMISTAT[®] is stronger or weaker than expected, ask your doctor or pharmacist.

If you have taken more PULMISTAT[®] than you should:

Talk to your doctor or pharmacist if you have taken more PULMISTAT[®] than you should.

If you forget to take PULMISTAT[®]

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

Excessive doses of PULMISTAT[®] may be associated with the following symptoms: sleepiness, nausea, vomiting, diarrhea, drowsiness, or reduced blood pressure. These effects may be reduced or alleviated with dose reduction or stopping the medicine. If such effects persist after stopping the medicine, talk to your doctor or pharmacist.

Effects that can occur if you stop taking PULMISTAT[®]

None.

4. Possible side effects

Like all medicines, this medicine can cause side effects in subjects who are sensitive to its ingredients.

If you experience any of the following side effects, stop taking PULMISTAT[®] and immediately consult with your doctor or seek for immediate medical assistance:

- Skin rash

This is a very serious side effect. If you experience this side effect, it may show that you may have severe allergy to PULMISTAT[®] that may require emergent medical intervention or hospital admission.

This very serious side effects occurs rarely.

If you get any of the following talk to your doctor:

- Sleepiness
- Nausea
- Diarrhea

These are mild side effects of PULMISTAT[®]

Please talk to your doctor or pharmacist if you have any side effects not listed in this leaflet.

Reporting of the side effects

If you have any side effects listed or not listed in this leaflet, talk to your doctor, pharmacist or nurse. Also you can report the side effects by clicking on the “Drug Side Effect Reporting” button at www.titck.gov.tr or by calling Turkish Pharmacovigilance Centre (TÜFAM) at 0 800 314 00 08. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PULMISTAT[®]

Keep PULMISTAT[®] out of the sight and reach of children.

Do not store above 25°C.

Do not use after expiry date

Do not use PULMISTAT[®] after the expiry date which is stated on the label and carton.

If you notice any compromise in the product and/or its packing, do not take PULMISTAT[®].

Marketing Authorization Holder:

Santa Farma İlaç San. A.Ş.
Okmeydanı, Boruçiçeği Sok. No: 16
34382 Şişli/İSTANBUL
Tel: (+90 212) 220 64 00
Fax: (+90 212) 222 57 59

Manufacturing site:

Santa Farma İlaç Sanayii A.Ş.
GEBKİM 41455 Dilovası-KOCAELİ
Tel: (+90 262) 674 23 00
Fax: (+90 262) 674 23 21

This document has been approved on: (date)