

PATIENT INFORMATION LEAFLET

FLUIBRON[®] 15 mg/5 ml pediatric syrup

Administered orally.

- **Active Substance:** 5 ml (1 spoon) syrup contains 15 mg ambroxol HCl.
- **Excipients:** 70 % sorbitol solution (E420), glycerine, propylene glycol, hydroxyethyl cellulose 4000, benzoic acid, citric acid monohydrate, sodium saccharine, raspberry flavor and demineralized water.

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

- *Keep the patient 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 these Usage Instructions:

1. *What is FLUIBRON[®] and what is it used for?*
2. *Issues prior to the use of FLUIBRON[®]*
3. *How is FLUIBRON[®] used?*
4. *What are the possible side effects?*
5. *How to store FLUIBRON[®]*

Are explained.

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

- FLUIBRON[®], is an expectorant drug, diluting the sputum excretion and facilitating its excretion. Therefore, by facilitating discharge of sputum, it relieves respiratory distress and reduces cough.
- FLUIBRON[®], is presented in honey-colored bottles, containing 150 ml syrup, together with 5 ml plastic spoon. It has a colorless, clear syrup appearance.
- FLUIBRON[®] is used as an expectorant in acute and chronic respiratory tract conditions, involving thick and sticky sputum.

2. Issues prior to the use of FLUIBRON[®]

DO NOT USE FLUIBRON[®] in case of following

- If you are hypersensitive to bromhexine or ambroxol.

USE FLUIBRON[®] CAUTIOUSLY in case of following

- If you have kidney or liver condition or peptic ulcer (ulcer, developing in stomach, duodenum or the lower part of larynx), use the drug very carefully.

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

The use of FLUIBRON[®] with food and beverage

Syrup is administered after meals.

Pregnancy

Please consult your physician or pharmacist before using the pharmaceutical.

Since adequate clinical studies are not available, in the first trimester of pregnancy, it may be used only in case necessary, by making a benefit-risk assessment.

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.

It must be used very carefully in lactating women.

Use of vehicles and machinery

There is no information that FLUIBRON[®] affects the ability to drive and operate machinery; caution must be exercised.

Important information concerning some of the excipients, contained in FLUIBRON[®]

FLUIBRON[®] contains sorbitol (E420). If you have been told by your physician that you had intolerance to certain sugars, you should consult your physician before taking this medicinal product.

Use with other pharmaceuticals

- Do not use together with cough suppressant drugs, such as codeine, which may prevent discharge of sputum.
- Atropine (a drug used to dilate pupils and prevent stopping of heart, yet which decreases secretion of sweat, saliva and mucus secretions) and amantadine (a drug group, used in the treatment of Parkinson's Disease) which has antimuscarinic action (the drug group, blocking a substance called acetylcholine in nervous system), tricyclic antidepressants (a drug group, used in the treatment of depression), haloperidol (a drug group, used in the treatment of schizophrenia), antihistamines (a drug group, used in the treatment of allergy), procainamide (a drug group, used in the treatment of cardiac arrhythmia) and other drugs (ipratropium, a drug group, used in the treatment of chronic lung conditions) could cause accumulation of mucosa secretions.
- Has no interaction with cardiac glycosides (a drug group, used in heart failure), corticosteroids (a hormone group, used in pain and inflammation treatment), bronchodilators (drugs, expanding airways in lungs, called bronchi), diuretics (drugs, increasing production of urine) and antibiotics (drugs effective against microorganisms).

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 FLUIBRON[®] used?

- **Instructions for appropriate usage and dosage/application frequency:**

In children:

Between ages 0-2: 1/2 spoon 2 times a day (2.5 ml),

Between ages 2-5: 1/2 spoon 3 times a day (2.5 ml),

Between ages 5-12: 1 spoon 2-3 times a day (5 ml),

The doses may be doubled in the beginning of treatment.

Your physician will tell you the duration of your treatment with FLUIBRON[®].

- **Administration route and method:** Administered orally. May be diluted with water or fruit juice.

- **Different age groups**

Use in children: For use in infants and children between 0 to 12 years of age, see "Instructions for Appropriate use and dose/administration frequency" section.

Use in elderly: There are no special conditions for use in elderly patients.

- **Special usage conditions:**

Kidney/liver failure: Caution must be exercised in patients with kidney, liver diseases and peptic ulcer.

In case you have an impression that FLUIBRON[®] is too weak or too strong, talk to your physician or your pharmacist.

If you used more FLUIBRON[®] than you should have used

Until today, no cases of toxicity has been reported in humans. In case of overdose, gastric lavage is employed and symptomatic and supportive treatment is applied.

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

If you forget to use FLUIBRON[®]

Do not take double doses to compensate for forgotten doses.

Effects, which may occur on termination of treatment with FLUIBRON[®]

Unknown

4. What are the possible side effects?

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

If any of the following occurs, stop taking FLUIBRON[®] and inform your doctor IMMEDIATELY and refer to the emergency service of the nearest hospital.

- Skin eruptions
- Change in mucosa.
- Swelling in the face
- Difficulty in breathing

All these are serious side effects.

In case you have one of these, it means that you have a serious allergy to FLUIBRON[®].

You may need emergency medical attention or hospitalization.
All of these serious side effects are seen very rarely.

If you observe any of the following, inform your doctor immediately and refer to the emergency room of the nearest hospital

- Skin eruptions

These are serious side effects. Immediate medical response may be required. Serious side effects are seen very rarely.

If you experience any of the following, inform your physician:

- Nausea, vomit
- Abdominal pain
- Diarrhea
- Fatigue
- Headache
- Itching

These are mild side effects of FLUIBRON®.

In case you observe any side effects, which are not mentioned in these usage instructions, please inform your physician or your pharmacist.

Reporting of side effects

In case of a side effect, which is given in the Usage Instructions 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. How to store FLUIBRON®

Keep FLUIBRON® away from reach and sight of children and in package.

Keep at room temperature below 25°C.

Use in compliance with expiry date.

Do not use FLUIBRON® after the expiry date, given on the pack.

License Holder: Santa Farma İlaç Sanayi A.Ş.

Okmeydanı, Boruçiçeği Sokak, 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

These usage instructions have been approved on .././....