

PATIENT INFORMATION LEAFLET

Patient Information Leaflet for Butatex Syrup

It is taken orally.

- **Drug Substance:** Each 5 ml syrup contains 7.5 mg butamirate citrate (1.5 mg / ml).
- **Excipients:** Sorbitol is liquid non-crystalline (70%), glycerol, sodium benzoate, raspberry aroma, sucralose, fructose, citric acid monohydrate, sodium citrate dihydrate, tutti frutti aroma, azorubine, purified water.

Before start using this medicine, first you read carefully this LEAFLET, because it contains important information for you.

- *Keep this leaflet. Later you may need to read it again.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine is prescribed for you personally, you should not give to others.*
- *During the use of this medicine if you go to doctor or hospital, say to your doctor that you use this medicine.*
- *Please abide exactly by what it is written in this instruction. Except from the dose that recommended for you about the medicine, do not use **high or low** dose.*

In this leaflet:

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Titles include.

1.What is BUTATEX and what it is used for?

BUTATEX is a drug in the form of syrup, which contains butamirate citrate as the active ingredient.

- BUTATEX belongs to a group of drugs called cough suppressants.
- BUTATEX syrup is available with colored 100 ml bottles with vistop cap.
- BUTATEX is used for symptomatic treatment of cough caused by various causes.

2.Points to take into account before using BUTATEX

DO NOT USE BUTATEX in the following cases

Do not use if you / your child are allergic to any of the excipients in the composition of butamirate or BUTATEX (see list of excipients).

Do not use if your child is under 3 years old.

USE BUTATEX CAREFULLY in the following cases

If you / your child are also taking other expectorant medications, you should be careful. It is recommended not to use BUTATEX at the same time as such drugs.

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

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

Pregnancy

- Consult your doctor or pharmacist before using this medication.
- If you are pregnant, it is recommended that you do not use BUTATEX for the first three months. You can only use BUTATEX at a later date if your doctor decides that it is a strict requirement.
- If you notice that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

- Consult your doctor or pharmacist before using this medication.
- If you are breastfeeding, consult your doctor before taking BUTATEX.

Vehicle and machine use

- BUTATEX can make you feel sleepy. For this reason, use caution when driving and operating machinery or other tasks that require attention.

Important information about some of the excipients contained in BUTATEX

- BUTATEX contains sorbitol and fructose. If you have already been told by your doctor that you are susceptible to certain sugars, contact your doctor before taking this medicinal product.
- BUTATEX contains less than 1 mmol (23 mg) of sodium per 100 ml; that is essentially sodium-free.
- BUTATEX contains azorubin as coloring agent. May cause an allergic reaction.

Concomitant use with other drugs

If you are using other drugs that have expectorant properties, please inform your doctor.

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

3.How to use BUTATEX?

Instructions for proper use and frequency of dosage / administration:

Unless otherwise recommended by the doctor, use the following doses for yourself / your child:

Not recommended for children under 6 years.

6-12 year old children: 2/3 scale (10 ml) 3 times a day

Adolescents over the age of 12 (adolescents): 1 scale 3 times a day (15 ml)

Adults: 1 scale (15 ml) 4 times a day

Do not use BUTATEX for more than 1 week unless your doctor makes a different recommendation.

Application route and method:

BUTATEX is used orally.

Use the graduated scale to adjust the dose of your medicine. Wash and dry the graduated scale each time it is used.

Different age groups:

Use in children:

BUTATEX Syrup is not recommended for children under 6 years.

Elderly Use:

The use of BUTATEX in the elderly has not been investigated.

Special use cases

BUTATEX has not been studied in patients with renal or hepatic impairment.

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

If you used more BUTATEX than you should:

Talk to a doctor and pharmacist if you have used more than you should use from BUTATEX.

If you forget to use BUTATEX:

Do not take double doses to compensate for forgotten doses.

In the event of an overdose of BUTATEX, the following symptoms may occur: drowsiness, nausea, vomiting, diarrhea, dizziness and drop in blood pressure. These effects may disappear when dose is reduced or treatment is discontinued. If these effects persist when the medication is discontinued, consult your doctor or pharmacist.

Effects that may occur when treatment with BUTATEX is terminated:

None.

4.What are the possible adverse effects?

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

Side effects are classified as follows:

Very common (visible in at least one of 10 patients)

Common (less than one out of 10 but more than one out of 100)

Uncommon (less than one out of 100 but more than one out of 1000)

Infrequent (less than one out of 1000 patients but more than one out of 10000 patients)

Very rare (less than one in 10 000 patients may be seen)

Unknown (Unable to estimate from the available data)

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

Rare:

- Sleeping state
- Nausea
- Diarrhea
- Urticaria

These are mild side effects of BUTATEX.

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

5.How to store BUTATEX?

Keep BUTATEX out of the reach of children and in its packaging.

Store at room temperature below 25 ° C.

Use in accordance with the expiry date.

Do not use BUTATEX after the expiry date on the packaging.

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

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The place of Production: Drogan İlaçları San. Ve Tic. A.Ş.
Çubuk – ANKARA

This leaflet has been approved under the date of 13/06/2015.