

PATIENT INFORMATION LEAFLET

BUTIROL FORT 22.5 mg/5 ml syrup

It is taken orally.

- **Active ingredient:** Each 5 ml of syrup contains 22.5 mg of butamirate citrate
- **Excipients:** Sorbitol (70% non-crystalline), sodium benzoate, raspberry flavor (FM00192), glycerol, sucralose, fructose, citric acid monohydrate, sodium citrate dihydrate, tutti frutti flavor (FM04706), azorubin (carmoisine), purified water

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

- *Keep this leaflet. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *When you go to the doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high** or **low** doses other than the dose recommended to you about the drug.*

In this leaflet:

- 1. What is BUTIROL FORT and what is it used for?**
- 2. Things to consider before using BUTIROL FORT**
- 3. How to use BUTIROL FORT?**
- 4. What are the possible side effects?**
- 5. Storing condition for BUTIROL FORT**

Headings are included.

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

- BUTIROL FORT is a light pink colored, clear, fruit flavored solution presented in a 100 ml Type II amber colored glass bottle with a PE vistor cap, with a 5 ml measuring spoon.
- BUTIROL FORT is a syrup form drug containing butamirate citrate as an active ingredient.
- BUTIROL FORT belongs to a group of drugs called "cough suppressants".
- BUTIROL FORT is used in the symptomatic treatment of cough caused by various reasons.

2. Things to consider before using BUTIROL FORT

DO NOT USE BUTIROL FORT in the following conditions

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

If your child is under 3 years old, do not use BUTIROL FORT.

USE BUTIROL FORT CAREFULLY in the following cases

You should be careful if you/your child are also taking other expectorant medications. It is recommended that BUTIROL FORT should not be used simultaneously with such drugs.

Not recommended under 6 years old.

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

Consult your doctor or pharmacist if cough worsens or persists for more than 7 days and/or fever or persistent headache occurs.

Using BUTIROL FORT with food and drink

BUTIROL FORT has no interaction with food and drink.

You can use BUTIROL FORT on an empty stomach or on a full stomach.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant, it is recommended not to use BUTIROL FORT for the first three months.

In the later period, you can use BUTIROL FORT only if your doctor decides that it is absolutely necessary.

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

Breast-feeding

Consult your doctor or pharmacist before using this medication.

If you are breastfeeding your baby, consult your doctor before taking BUTIROL FORT.

Vehicle and machine use

BUTIROL FORT may make you feel sleepy. For this reason, be careful when driving vehicles, machines or doing other work that requires attention.

Important information about some of the ingredients of BUTIROL

BUTIROL FORT 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 BUTIROL FORT. If you need to use BUTIROL FORT as 5 ml 4 times a day, BUTIROL FORT may have a mild laxative effect due to the sorbitol it contains. Its calorific value is 26 kcal/g sorbitol.

BUTIROL FORT also contains sucralose and fructose as sweeteners. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

BUTIROL FORT contains azorubin as a dyestuff. May cause allergic reactions.

Concomitant use with other drugs

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

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3. How to use BUTIROL FORT?

Instructions for proper use and dose / frequency of administration:

Unless recommended otherwise by the doctor, use the doses specified for yourself/your child.

Not recommended for use in children under 6 years of age.

Children aged 6-12 years (including 6 and 12 years): 1 spoon (5 mL) 2 times a day

Adolescents over 12 years of age: 1 spoon (5 mL) 3 times a day

Adults: 1 spoon (5 mL) 4 times a day

Do not use BUTIROL FORT for longer than 7 days, unless your doctor advises differently.

Administration route and method:

- BUTIROL FORT is used orally.
- Use the measuring spoon to adjust the dose of your medicine. Wash and dry the measuring spoon after each use.

Different age groups:**Use in children:**

BUTIROL FORT Syrup should not be used in children under 3 years of age.

The use of BUTIROL FORT in children under 6 years of age is not recommended.

Use in the elderly:

The use of BUTIROL FORT in the elderly has not been studied.

Special use cases:**Kidney/Liver failure:**

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

If you have the impression that the effect of BUTIROL FORT is too strong or weak, talk to your doctor or pharmacist.

If you use more BUTIROL FORT than you should

If you have used more than you should use from BUTIROL FORT, talk to a doctor or pharmacist.

If you forget to use BUTIROL FORT

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

In case of overdose of BUTIROL FORT, the following symptoms may occur: Drowsiness, nausea, vomiting, diarrhoea, drowsiness and low blood pressure. These effects may disappear when the dose is reduced or treatment is discontinued. If these effects persist when the drug is discontinued, consult your doctor or pharmacist.

Effects that may occur when treatment with BUTIROL FORT is terminated

Not available.

4. What Are The Possible Side Effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in BUTIROL FORT.

Side effects are listed as follows according to their frequency of occurrence.

- Very Common (may be seen in at least 1 in 10 patients)
- Common (less than 1 in 10 patients but more than 1 in 100 patients)
- Uncommon (affects less than 1 in 100 but more than 1 in 1,000 patients)
- Rare (may affect less than 1 in 1,000 patients but more than 1 in 10,000 patients)
- Very Rare (may affect up to 1 in 10,000 patients)
- Unknown (cannot be estimated from the available data)

If any of the following occur, stop using BUTIROL FORT and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Skin rash

This is a very serious side effect.

If you have this side effect, it means you have a serious allergy to BUTIROL FORT.

You may need emergency medical attention or hospitalization.

This very serious side effect is very rare.

Tell your doctor if you notice any of the following:

Rare:

- Sleeping state
- Nausea, diarrhea
- Urticaria (hives)

These are the mild side effects of BUTIROL FORT.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storing condition for BUTIROL FORT

Keep BUTIROL FORT out of the sight and reach of children and in its package.

Store at room temperature below 25°C.

Use in accordance with expiration dates.

Do not use BUTIROL FORT after the expiry date on the package.

Do not use BUTIROL FORT if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

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