

PACKAGE LEAFLET: Information for the user

BUTAMOL

Syrup – 2 mg / 5 ml

(Salbutamol sulphate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Butamol is and what it is used for
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1. WHAT BUTAMOL IS AND WHAT IT IS USED FOR

Butamol syrup contains the active substance salbutamol sulphate. Salbutamol is a direct-acting sympathomimetic with mainly beta-adrenergic activity and has selective action on β_2 -receptors (agonist).

Salbutamol sulphate is used:

- as bronchodilator in reversible airways obstruction;
- for the treatment and prophylaxis of bronchial asthma;

- for the treatment of other diseases like bronchitis and emphysema accompanied with reversible airways obstruction.

Your doctor may have given Butamol for another purpose. Ask your doctor if you want to know why you have been given this medicine.

2. BEFORE YOU TAKE BUTAMOL

Do not take Butamol if:

- you are hypersensitive to salbutamol sulphate or to any of the other ingredients of the syrup;
- you are using nonselective β -blockers, for example: propranolol.

Take special care with Butamol

Salbutamol should be used with caution in patients who suffer from: thyrotoxicosis (hyperthyroidism), myocardial insufficiency, risk for the prolongation of QT interval, arrhythmias and hypertension.

In diabetic patients ketoacidosis may appear, therefore the level of blood glucose should be followed during the use of salbutamol.

Caution should be done during concomitant administration of salbutamol with theophylline or corticosteroids in case of treatment of severe asthma because the patient's condition may deteriorate and hypokalemia may appear.

Caution should be done during concomitant administration of salbutamol with diuretics because hypokalemia may appear.

You should discuss your treatment with your doctor or pharmacist if you have any of the symptoms mentioned above.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Butamol.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not forget to inform your doctor for the treatment with Butamol if you receive any other medicine during treatment.

Butamol is not advisable to be used mixed with other preparation in liquid forms.

Salbutamol and other nonselective β -blockers like propranolol, usually should not be used together.

Salbutamol should not be used at the same time with theophylline, diuretics, and with corticosteroids because the risk for hypokalemia is increased.

It is advisable to do the continuous control of the concentration of potassium in blood in patients who suffer from severe asthma and may be treated with the combination of therapies listed above.

Taking Butamol with food and drinks

No data are available.

Pregnancy and breastfeeding

Ask for the advice of your pharmacist or doctor before you take this drug.

The use of salbutamol during pregnancy or breast-feeding should be done only in cases it is strictly necessary, and only after the therapeutic benefits for the mother with the possible risk for the fetus or child have been estimated.

Driving and using machines

There is no evidence that this drug can affect your ability to drive or use machinery.

Important information about some of the ingredients of Butamol

Butamol syrup contains:

- sucrose - if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product;
- methylhydroxybenzoate (nipagin) - may cause allergic reactions (possibly delayed).

3. HOW TO TAKE BUTAMOL

Always take Butamol according to your doctor advice. Check with your doctor or pharmacist if you are not sure. If you feel that the effects of Butamol are too strong or too weak, talk to your doctor or pharmacist.

Adults, the usual effective dose is 4 mg (or 10 ml syrup) 3-4 times a day.

If the sufficient bronchodilatation is not achieved, the single dose may be increased up to 8 mg.

In sick elderly or they who are known to have pronounced hypersensitivity to β_2 adrenergic stimulants, it is recommended that treatment should start with 2 mg, 3 - 4 times a day.

Children

2-6 years old: 1 - 2 mg (2.5 ml - 5 ml), 3 - 4 times a day

6-12 years old: 2 mg (5 ml), 3 - 4 times a day

Over 12 years old: 2 - 4 mg (5 ml - 10ml), 3 - 4 times a day.

If you take more Butamol than you should

If you take more Butamol than you should, or if the children take it accidentally, please contact your doctor, the nearest hospital, or call the emergency to take an opinion for the risk and advices about the actions to be taken.

If you forget to take Butamol

If you forget to take one dose (or more), take the next dose in its usual time. Do not take a double dose (or higher) to make up the forgotten dose (doses).

If you have further questions about the use of this drug, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Butamol can cause side effects, although not everybody gets them.

Sometimes they are serious, most of the times not. Do not be alarmed by this list of possible side effects. You may not get any of them.

Most side effects are dose - related and they disappear when the dose is reduced or the treatment is interrupted.

Some side effects may happen at the beginning of treatment and disappear spontaneously during treatment.

Inform your doctor if any of the side effects below bothers you.

Side effects are as follows:

Very common (may affect more than 1 in 10 people)

- fine tremor of skeletal muscles, particularly of the hands.

Common (may affect up to 1 in 10 people)

- muscular cramps;
- headache;
- tachycardia;
- palpitations.

Rare (may affect up to 1 in 1,000 people)

- hypokalemia after high doses;
- vasodilatation of peripheral blood vessels.

Very rare (may affect up to 1 in 10,000 people)

- sleep and behavioral disorders;
- muscle tension;
- myocardial ischemia.

Hypersensitivity reactions were observed with symptoms such as: paradoxical bronchospasm, urticaria and angioedema, hypotension, collapse.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE BUTAMOL

Keep this medicine out of the reach and sight of children.

Do not take Butamol after the expiry date which is stated on the package.

Store at a temperature between 10°C - 25°C.

Store in the original package protected from light.

6. OTHER INFORMATION

What Butamol 2 mg / 5 ml syrup contains

The active substance is salbutamol sulphate.

5 ml syrup contain salbutamol sulphate equivalent to 2 mg salbutamol.

The other ingredients are: citric acid monohydrate, sodium citrate, sucrose, methyl p-hydroxybenzoate (nipagin), essence citri, purified water.

Content of the pack

Carton box with one amber glass bottle of 150 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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