

# BUTALIN

## Inhaler Bronchodilator CFC - Free

### Composition

Each inhalation (actuation) contains:

**Active ingredient:** Salbutamol base (micronized) 100mcg

**Excipients:** Oleic acid, absolute ethanol, and norflurane.

### Properties

Salbutamol, the active ingredient of BUTALIN, is a selective beta<sub>2</sub>-adrenergic agonist that produces marked bronchodilation with minimal or no effect on the cardiovascular system. In addition, it inhibits the release of mediators of immediate hypersensitivity from cells, especially from mast cells. This hypersensitivity reaction is generally considered to be the primary trigger of the allergic asthma syndrome.

After administration, the initial response is within 5 to 15 minutes and it usually lasts for 4 to 6 hours when administered within the recommended doses.

### Indications

BUTALIN inhaler is indicated both for the treatment and prophylaxis of bronchial asthma as well as for the treatment of other conditions associated with reversible airway obstruction such as bronchitis and emphysema.

BUTALIN inhaler acts rapidly and may be used when necessary to relieve attacks of acute dyspnoea. Doses may be taken prophylactically before exertion or to prevent exercise-induced asthma.

Because BUTALIN is long-acting, it is ideally suited for routine maintenance therapy in chronic asthma and chronic bronchitis.

Due to its selective action on the bronchi and its lack of effects on the cardiovascular system, BUTALIN inhaler is suitable for treating bronchospasm in patients with coexisting heart disease or hypertension.

### Dosage

#### Adults

For the relief of acute bronchospasm and for managing intermittent episodes of asthma, one or two inhalations (100 - 200mcg) may be administered as a single dose.

For chronic maintenance or prophylactic therapy, one or two inhalations (100 - 200mcg) may be administered three or four times a day.

For the prevention of exercise-induced bronchospasm, two inhalations (200mcg) should be taken before exertion.

#### Children

For the relief of acute bronchospasm in the management of episodic asthma, one inhalation (100mcg) may be administered and to be increased to two inhalations (200mcg) if necessary.

For routine maintenance or prophylactic therapy, one inhalation (100mcg) can be administered three or four times a day. These doses may be increased to two inhalations (200mcg) if necessary.

For the prevention of exercise-induced bronchospasm, one inhalation (100mcg) should be taken before exertion.

For optimum results, in some patients, BUTALIN inhaler should be used regularly. The bronchodilator effect of each administration lasts for at least four hours, except in patients whose asthma is becoming worse. Such patients should be warned not to increase their usage of inhaler, but should seek medical advice in case treatment with an inhaled and/or systemic glucocorticosteroid is indicated.

#### Directions for use

- 1- Remove the cover from the mouthpiece and shake the inhaler vigorously.
- 2- Holding the inhaler with the mouthpiece down towards your mouth and putting your thumb under the mouthpiece and your index over the bottom of the canister, breathe out gently (but not fully) and then immediately place the mouthpiece in the mouth and close your lips around it.
- 3- After starting to breathe in slowly and deeply through your mouth, press the inhaler firmly by using your index to release BUTALIN and continue to breathe in.
- 4- Hold your breath for 10 seconds, or as long as it is comfortable, before breathing out slowly.
- 5- If you are to take a second inhalation, you should wait at least 1 minute before repeating steps 2, 3 and 4.
- 6- After use replace the cover on the mouthpiece.
- 7- **Cleaning:** Remove the canister, rinse the actuator in warm water, dry, and replace canister.

#### Notes

- It is dangerous to exceed the recommended dose.
- **Children:** BUTALIN inhaler should be used under the supervision of a responsible adult and only as instructed by the doctor.
- **Caution:** The canister is pressurized. Do not puncture, break, or burn, even when empty.

### Contraindications

It is contraindicated in patients with a history of hypersensitivity to any of its components.

### Precautions

In the event of a previously effective dose of BUTALIN inhaler failing to give relief for at least three hours, the patients should be advised to seek medical advice in order that any necessary additional steps may be taken.

Salbutamol should be used with caution in patients with hyperthyroidism, hypertension, myocardial insufficiency, arrhythmias, or susceptibility to QT-interval prolongation.

Diabetic patients should use salbutamol with caution. However, caution is particularly recommended with intravenous administration rather than other dosage form. Blood glucose monitoring is usually recommended in such patients as ketoacidosis has been reported in some cases.

As with other beta<sub>2</sub>-adrenoceptor stimulant therapy, high doses of salbutamol may be dangerous in some patients as potentially serious hypokalaemia may be precipitated. Particular caution is required in severe asthma, as this effect may be potentiated by concomitant treatment with theophylline and its derivatives, corticosteroids, and diuretics, and by hypoxia. Plasma potassium concentrations should therefore be monitored in severe asthma.

**Pregnancy:** BUTALIN inhaler has particular advantages as a means of drug administration during pregnancy because its therapeutic action can be achieved by plasma drug concentrations which are considered too small to produce an apparent ill consequence to the fetus; this includes its well established use in the management of premature labour. However, as adequate and well-controlled studies in human have not been done, it is better to be used with caution.

**Lactation:** It is recommended to use salbutamol with caution during lactation as it is not known whether it is distributed into breast milk of humans.

### Side Effects

The inhaler drug-delivery system, using salbutamol in microgram dosage, is usually well tolerated as it delivers the drug directly to the bronchi and therefore provides effective relief more rapidly with smaller doses and fewer side effects.

Fine tremor (usually hands) and headache have been rarely reported. These effects usually disappear with continued treatment. There have been very rare reports of transient muscle cramps.

Hypersensitivity reactions including angioedema, urticaria, and paradoxical bronchospasm have been reported very rarely.

As with other beta<sub>2</sub>-adrenoceptor stimulant therapy, salbutamol may rarely cause nervous tension, peripheral vasodilatation, palpitation, and tachycardia. However, these effects are seldomly troublesome with the use of the inhaler dosage form.

Hypokalaemia may be precipitated with the administration of high doses of salbutamol.

### Overdosage

The preferred antidote for overdosage with salbutamol is a cardioselective beta-blocking agent, but beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

### Drug Interactions

Increased risk of hypokalaemia has been reported if high doses of salbutamol are given concomitantly with high doses of corticosteroids, diuretics (e.g., acetazolamide, loop diuretics, and thiazide), or theophylline (See: Precautions).

### Presentation

**BUTALIN** inhaler: Canister of 200 doses.

\* Store at a temperature of 15 - 25°C. Avoid storage in direct sunlight or heat. Do not refrigerate.

#### THIS IS A MEDICAMENT

- Medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children.

Council of Arab Health Ministers,  
Union of Arab Pharmacists

Any information? Call Our Toll Free No. (971) 800-499



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