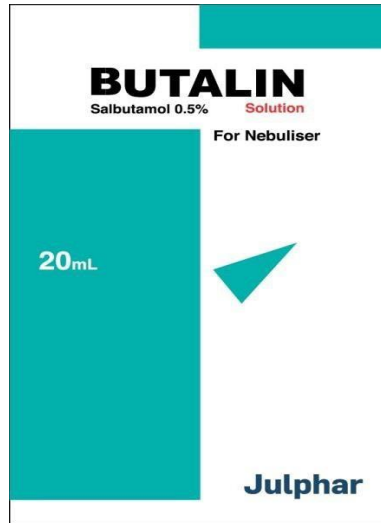


**Important Safety Information (Butalin BUTALIN 0.5% Solution for Nebuliser Salbutamol
5mg/mL-)**

Patient Education Guide

BUTALIN 0.5% Solution for Nebuliser



Objective of this educational material:

This educational material is essential to ensure the safe and effective use of the product and appropriate management of the important selected risks.

Presentation:

BUTALIN 0.5% solution for nebuliser is available in packs of one bottle (20mL each) with the specially marked dropper.

Composition:

Each 1mL of the solution contains Salbutamol (as sulphate) 5mg.

Indications:

BUTALIN 0.5% solution for nebuliser is indicated for use in the routine management of chronic bronchospasm unresponsive to conventional therapy and in the treatment of acute severe asthma.

How to use your BUTALIN 0.5% solution for a nebuliser?

Your doctor may have prescribed either intermittent (occasional short bursts) or continuous treatment with BUTALIN Solution.

Intermittent treatment:

Adults and adolescents aged 12 years and over:

The usual dose is 0.5 mL to 1 mL of BUTALIN Solution (2.5 to 5 mg salbutamol).

Some patients may require up to 2 mL (10 mg salbutamol).

Children aged 18 months to 12 years:

The usual dose is 0.5 mL to 1 mL (2.5 to 5 mg salbutamol) of BUTALIN Solution, given four times daily.

Your doctor may have told you to dilute the BUTALIN Solution with a sterile normal saline solution before using it in the nebuliser. Remember to follow the instructions for dilution.

Continuous treatment:

The usual dose is 1 to 2 mg of salbutamol per hour.

This dose can be obtained by diluting 1 or 2 mL of BUTALIN Solution to 100 mL with sterile normal saline solution to produce a solution containing 50 or 100 micrograms/mL of salbutamol and inhaling the mist from a suitable nebuliser.

Instructions for use

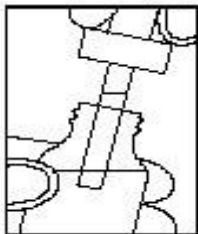


Figure 1

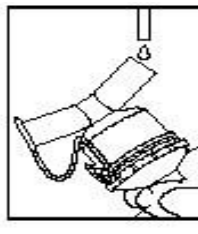


Figure 2

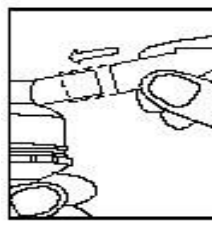


Figure 3

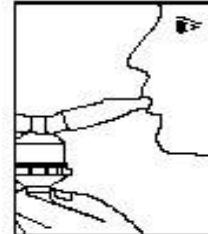


Figure 4

1. Prepare the nebuliser for filling. Please follow the manufacturer's instructions.
2. Draw the appropriate volume of BUTALIN Solution into the specially marked dropper that comes with each multi-dose bottle (see Figure 1) and put it in the nebuliser bowl and taking care not to touch the tip of the dropper (see Figure 2).
3. Add the right amount of sterile normal saline solution (make sure your doctor has told you how much to use).
4. Put the top on the nebuliser bowl and shake it gently to mix the contents.
5. Connect the nebuliser with the mouthpiece or face mask (see Figure 3).
6. Sit in a comfortable, upright position, place the mouthpiece in your mouth (or put on the face mask) (see Figure 4), and turn on the nebuliser.
7. Breathe as calmly, deeply, and evenly as possible until no more mist is formed in the nebuliser chamber (about 5 to 15 minutes). At this point, the treatment is finished.
8. After use throw away any solution remaining in the nebuliser bowl. Clean your nebuliser in the recommended way.

- ❖ **To avoid microbial contamination, proper clean techniques should be used each time the bottle is opened. Examples of clean techniques include washing hands and applying clean gloves when needed. A person's surroundings are kept as clean as possible.**
- ❖ **Precautions should be taken to prevent contact of the bottle's dropper tip with any surface, including the nebuliser reservoir and associated ventilatory equipment. In addition, if the solution changes colour or becomes cloudy, it should not be used.**
- ❖ **Important information to avoid microbial contamination:**
 1. **Nebuliser devices should not be shared between patients.**
 2. **Cleaning and drying the nebuliser equipment between uses.**
- ❖ **If you used more BUTALIN Solution than you should**
 - **You should talk to your doctor as soon as possible. The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity, and metabolic effects including hypokalemia and lactic acidosis.**
- ❖ **If you forget to take BUTALIN Solution**
 - **If you forget a dose, take it as soon as you remember it.**
 - **However, if it is time for the next dose, skip the missed dose.**
 - **Do not take a double dose to make up for a forgotten dose.**
- ❖ **Special Precautions**
 - **Always use this medicine exactly as your doctor, pharmacist or nurse has told you.**
 - **BUTALIN Solution must only be used by inhalation from a nebuliser and must not be injected or swallowed.**
 - **Do not stop taking BUTALIN Solution without talking to your doctor.**
 - **Store below 30°C, protected from light.**
 - **The contents should be used within one month after the bottle is opened.**

For further information please refer to PIL

To report any side effect(s):

Reporting of suspected adverse reactions

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects, talk to your doctor or nurse. This includes any possible side effects even if they are not listed in this leaflet. You can also report side effects directly to Gulf pharmaceutical industries- JULPHAR or the National Pharmacovigilance and Drug Safety Center as follows:

- **The National Pharmacovigilance and Drug Safety Centre (NPC):**

Fax: +966-11-205-7662

Unified number: 19999

Toll-free phone: 8002490000

E-mail: npc.drug@sFDA.gov.sa Website: <https://ade.sFDA.gov.sa>

- **Gulf Pharmaceutical Industries (Julphar):**

Fax: + 96611 465 9921

E-mail: medical.affairs@julphar.net You can also report any side effects directly via the following link: <https://www.julphar.net/en/pharmacovigilance/how-do-i-report-an-adverse-reaction>

