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

HCP Guide

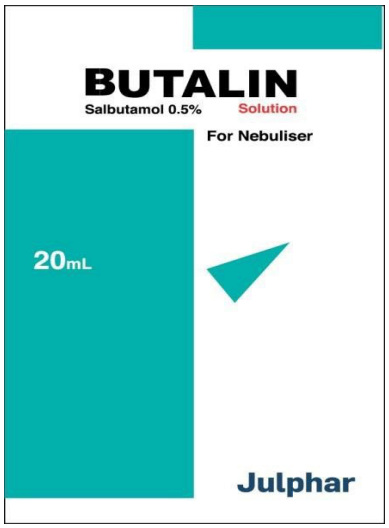
Objective of this educational material:

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

It is advised to be read carefully before prescribing or dispensing or administering the product.

What is BUTALIN 0.5% Solution for Nebuliser?

BUTALIN 0.5% Solution contains salbutamol. Each 1mL of the solution contains Salbutamol (as sulphate) 5mg.
Salbutamol, the active ingredient of BUTALIN, is a selective β2-agonist providing short-acting (4 - 6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airway obstruction.
At therapeutic doses, it acts on the β2adrenoceptors of bronchial muscle. With its fast onset of action, it is particularly suitable for managing and preventing asthma attacks.



Therapeutic indications

BUTALIN 0.5% solution is indicated in adults, adolescents and children aged 4 to 11 years. **BUTALIN 0.5%** is indicated for use in the routine management of chronic bronchospasm unresponsive to conventional therapy and in the treatment of acute severe asthma.

Posology and method of administration **BUTALIN** is for inhalation use only, to be breathed in through the mouth, under the direction of a healthcare professional, using a suitable nebuliser.
The solution should not be injected or swallowed

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BUTALIN may be administered intermittently or continuously. Salbutamol has a duration of action of 4 to 6 hours in most patients.

<u>Intermittent administration</u>

Adults:
BUTALIN 0.5 mL (2.5 mg of salbutamol) should be diluted to a final volume of 2 mL with sterile normal saline. This may be increased to 1 mL (5 mg of salbutamol) diluted to a final volume of 2.5 mL.

The resulting solution is inhaled from a suitably driven nebuliser until aerosol generation ceases. Using a correctly matched nebuliser and driving source this should take about ten minutes.

BUTALIN may be used undiluted for intermittent administration. For this, 2 mL of BUTALIN (10 mg of salbutamol) is placed in the nebuliser and the patient allowed to inhale the nebulised solution until bronchodilation is achieved.

This usually takes 3 - 5 minutes. Some adult patients may require higher doses of salbutamol up to 10 mg, in which case nebulisation of the undiluted solution may continue until aerosol generation ceases.

<u>Paediatric Population</u>

The same mode of administration for intermittent administration is also applicable to children. The minimum starting dosage for children under the age of 12 years is 0.5 mL (2.5 mg of salbutamol) diluted to 2 to 2.5 mL with sterile normal saline.
Some children (over the age of 18 months) may, however, require higher doses of salbutamol up to 5 mg.

Intermittent treatment may be repeated up to four times daily.
Children aged 12 years and over: Dose as per adult population. In infants under 18 months, the clinical efficacy of nebulized salbutamol is uncertain. As transient hypoxaemia may occur supplemental oxygen therapy should be considered.

Other pharmaceutical forms may be more appropriate for administration in children under 4 years old.

Continuous administration

BUTALIN solution is diluted with sterile normal saline to contain 50-100 micrograms of salbutamol per ml,
(1-2 mL solution made up to 100 mL with diluent). The diluted solution is administered as an aerosol by a suitably driven nebuliser. The usual rate of administration is 1-2 mg per hour.

Instructions for use

Dear Health care professional, the patients receiving treatment at home should be instructed to follow the following steps:

1. **The nebulizer should be prepared for filling according to the manufacturer's instructions.**
2. **The appropriate volume of BUTALIN solution should be drawn into the specially marked dropper that comes with each multi-dose bottle (as Figure 1) and put in the nebulizer bowl (as Figure 2).**

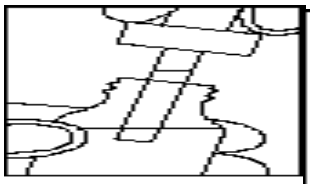

Figure 1

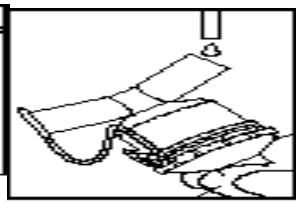

Figure 2

3. **The right amount of sterile normal saline solution should be added (as directed by the health care professional).**
4. **Close the nebulizer bowl and shake gently to mix the contents.**
5. **Connect the nebulizer with the mouthpiece or face mask (as Figure 3).**

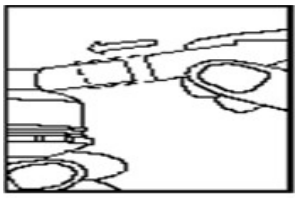

Figure 3

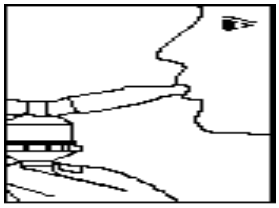

Figure 4

6. **The patients should set in a comfortable, upright position, place the mouthpiece in the mouth (or put on the face mask) (as in Figure 4), and turn on the nebulizer.**

7. **The patients should breathe calmly, deeply, and evenly as possible until no more mist is formed in the nebulizer chamber (about 5 to 15 minutes). They should be aware that at this point the treatment is finished.**
8. **The solution remaining in the nebuliser bowl should be discarded and the nebuliser should be cleaned in the recommended way.**

Note: 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 dropper tip of the bottle with any surface, including the nebuliser reservoir and associated ventilatory equipment. In addition, if the solution changes color or becomes cloudy, it should not be used.

- **Important information to avoid microbial contamination**

1. **Nebuliser device should not be shared between patients.**
2. **Cleaning and drying the nebuliser equipment between uses.**

- **If your patients used more BUTALIN Solution than they should**

They should talk to a 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 hypokalaemia and lactic acidosis.

- **If your patients forgot to take BUTALIN Solution**

If your patients forgot a dose, they should take it as soon as they remember it. However, if it is time for the next dose, the patients should skip the missed dose. The patients should not take a double dose to make up for a forgotten dose.

- **The patients should not stop taking BUTALIN solution without talking to their doctor.**

- **Special precautions for storage**

Store below 30°C, protected from light.
The contents should be used within one month after the bottle is opened.

Further information please refer to SPC or PIL

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:

To report any side effect(s):
• The National Pharmacovigilance and Drug Safety Centre (NPC):
Fax: +966-11-205-7662
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

• Gulf Pharmaceutical Industries (Julphar):
Call Julphar at: +966114631299
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

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