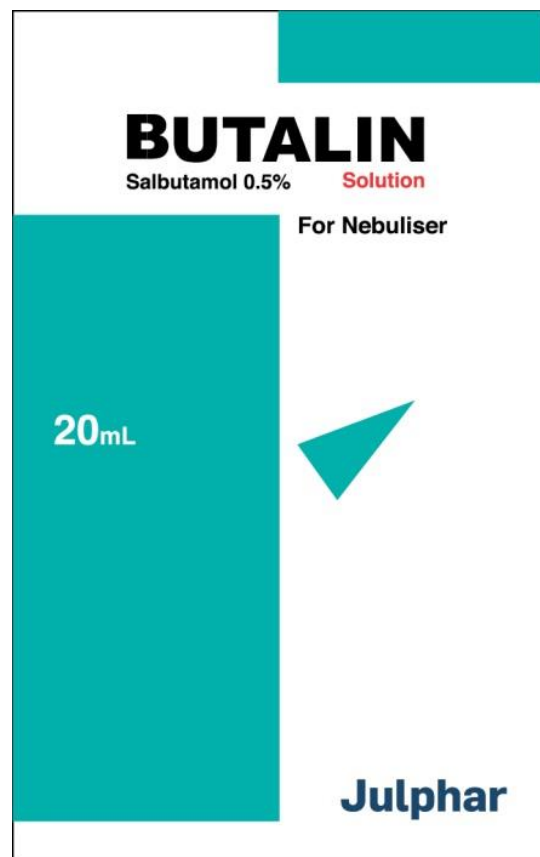


BUTALIN 0.5% Solution for Nebulizer



Presentation:

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

Composition:

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

Indications:

BUTALIN 0.5% solution for nebulizer 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 nebulizer?

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 nebulizer.

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 nebulizer.

Instructions for use

1. Prepare the nebulizer 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 nebulizer 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 nebulizer bowl and shake it gently to mix the contents.
5. Connect the nebulizer 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 nebulizer.
7. Breathe as calmly, deeply, and evenly as possible until no more mist is formed in the nebulizer chamber (about 5 to 15 minutes). At this point the treatment is finished.
8. After use throw away any solution remaining in the nebulizer bowl. Clean your nebulizer 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 dropper tip of the bottle with any surface, including the nebulizer reservoir and associated ventilatory equipment. In addition, if the solution changes color or becomes cloudy, it should not be used.



Figure 1

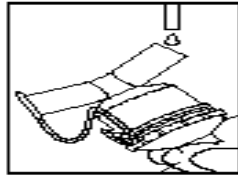


Figure 2

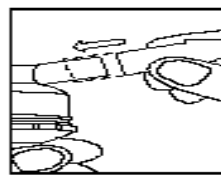


Figure 3



Figure 4

❖ Important information to avoid microbial contamination

1. Nebulizer device should not be shared between patients.
2. Cleaning and drying the nebulizer 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 nebulizer, 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.

To report any side effect(s) :

- **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: www.sfda.gov.sa/npc

- **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:

<http://julphar.net/adverse-drug-reaction-reporting-form>