Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Butamol 2.5 and Butamol 5. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking this medicine against the benefits it is expected to have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

This medicine is only part of a general plan to help you manage your asthma, or other chest conditions. You should discuss this plan with your doctor.

Ask your doctor to check your treatment plan regularly.

Keep this leaflet with the medicine.

You may want to read it again.

What Butamol is used for

The name of your medicine is Butamol 2.5 or Butamol 5. The medicine in your Butamol 2.5 and Butamol 5 is delivered through a device called a nebuliser.

Butamol contain a medicine called Salbutamol, which belongs to a group of medicines called beta-2-agonists. These work rapidly to open up the air passages in your lungs. Salbutamol is inhaled into the lungs for the treatment of Asthma.

Asthma is a disease where the lining of the lungs become inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke, air-borne pollution and other irritants. Salbutamol opens up the air passages in people suffering from asthma, bronchitis and other breathing problems.

It may also be used before exercise to keep your air passages open if you start to wheeze or have difficulty breathing each time you exert yourself.

Salbutamol inhalation may be used for the management of other conditions that are not mentioned above. Your doctor will be able to tell you about the specific condition for which you have been prescribed Butamol 2.5 or Butamol 5. This medicine is only available with a doctor's prescription.

Before you use it

When you must not use it

Do not use Butamol if you have an allergy to:

- Salbutamol or any other medicines used to treat breathing problems
- any other beta-2-agonist medicine
- any of the inactive ingredients mentioned at the end of this leaflet.

Check with your doctor if you are not sure whether any of these apply to you.

Before you start to use it

Tell your doctor if:

- 1. you have allergies to:
 - any other medicines
 - any other substances, including foods, preservatives or dyes.
- 2. you are pregnant, plan on becoming pregnant

- 3. you are breastfeeding or plan to breastfeed
- you have or have had any medical conditions, especially the following:
 - thyroid problems
 - heart problems
 - high blood pressure
 - diabetes
 - glaucoma.

Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Salbutamol may interfere with each other.

These include medicines used for:

- high blood pressure
- · heart problems
- · hay fever, cough and colds
- weight reduction
- · depression or other mood disorders.

Your doctor will advise you about continuing to take other medicines while you are receiving Salbutamol.

How to use it

How much to use

The usual dose is 5 mg for an adult and 2.5 mg for a child over 4 years, given every four to six hours. Your doctor will decide what dose and how often you should use Butamol.

The dosage you will be given will depend on your condition, what it is being used for and other factors, such as your age, and whether or not other medicines are being given at the same time.

Follow all directions given to you by your doctor or pharmacist carefully.

How to use it

The content of Butamol is inhaled through a nebuliser according to the manufacturer's instructions. The nebuliser changes the solution into a fine mist and delivers the medicine to your lungs when you inhale the mist through the mask.

Step 1: Remove the strip of Butamol from the carton and tear one ampoule from the strip. Open only one foil pack at a time, and use all 5 ampoules before opening the next foil pack.



Step 2: Never use a ampoule that has previously been opened. The ampoule may be opened by carefully holding the ampoule upright and twisting the top off.



Step 3: The content of the ampoule should be squeezed out into the nebuliser bowl.



The nebuliser should be assembled and used as directed by your doctor. After using the nebuliser, discard any solution remaining in the nebuliser bowl.

Follow the manufacturer's instructions on how to clean your nebuliser.

IMPORTANT: Fresh solution must be used for each dose. After the full dose has been given, any solution remaining in the nebuliser must be thrown away. Nebulisers must be cleaned after use according to the manufacturer's instructions.

If you forget to use it

If you miss a dose, do not worry. Just take the next dose at the normal time or earlier if you become wheezy or feel tight in your chest.

If you use too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have used too much Butamol. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you use too much, you may feel shaky, tremble or have a fast heart beat. These symptoms are usually mild side effects of Butamol. However, if they are severe or do not go away, it may be that you have taken too much Butamol.

While you are using it

Things you must do

If you have an Asthma Action Plan developed by your doctor, follow it closely at all times.

If the usual dose of Butamol is not giving as much relief as before, or you need to use it more often, please contact your doctor so that your condition can be checked.

This is important to ensure your breathing problem is controlled.

Continue using for as long as your doctor tells

Tell your doctor if you become pregnant while using this medicine.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using Butamol.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Butamol.

Visit your doctor regularly to check on your condition.

Things you must not do

Do not stop using Butamol, or lower the dose, without checking with your doctor.

Do not take any other medicines for your breathing problems without checking with your doctor.

Do not use it to treat any other conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Butamol.

Like all other medicines, it can cause some side effects. If they occur, most are likely to be minor or temporary. However, some maybe serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor immediately if you notice any of the following:

- a feeling of warmth
- difficulty breathing or worsening of your breathing problems
- swelling or severe rash
- fast or irregular heart beat
- pounding heart beat.

These may be serious side effects of Butamol. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following and they worry you:

- sore mouth, throat or tongue
- dry mouth
- coughing
- headache
- feeling anxious, nervous, restless or upset
- difficulty sleeping
- dizziness
- sweating
- trembling or shaking
- aching or weak muscles
- tingling or numbness in the hands or feet ('pins and needles')

- unpleasant taste in your mouth
- nausea or vomiting
- diarrhoea
- rash or itchy skin
- sore or puffy eyes.

These are the more common side effects of salbutamol. Mostly these are mild and short lived. Other side effects no listed above may also occur in some patients. If you notice any other side effects, check with your doctor. Some side effects may only be seen by your doctor.

Tell your doctor if you notice anything that is making you feel unwell.

After using it

Storage

Once you have opened each foil pack you need to note down the date of opening the foil lid. Add 3 months to this date and write it down in the space provided on the foil pack. Do not use the ampoules left in the tray after this date.

Keep your medicine in a cool dry place where the temperature stays below 25°C. It must be protected from light.

Do not store in direct sunlight or heat.

Do not leave in the car on hot days.

Keep your medicine where children cannot reach them.

Do not use after the expiry date on the carton has passed.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Do not store Butamol or any other medicine in the bathroom or near a sink.

Disposal

If your doctor tells you to stop using Butamol, or your medicine has passed its expiry date, ask your pharmacist what to do with any ampoules that are left over.

Product description

What it looks like

Butamol comes in 2 strengths:

- Butamol 2.5
- Butamol 5.

Each pack of Butamol contains 30 plastic ampoules. Each ampoule contains 2.5 mL of clear, colourless liquid.

Ingredients

The active ingredient in Butamol is Salbutamol (as Salbutamol sulfate):

- each Butamol 2.5 ampoule contains 2.5 mg of salbutamol in 2.5 mL of solution
- each Butamol 5 ampoule contains 5 mg of salbutamol in 2.5 mL of solution.

Butamol ampoules also contain:

- sodium chloride
- water for injections
- sulfuric acid.

Butamol is sterile and preservative free.

Supplier

Aspen Pharma Pty Ltd

34-36 Chandos Street St Leonards NSW 2065 Australia

Australian Registration Numbers:

Butamol 2.5 - Aust R 158051 Butamol 5 - Aust R 158052

Published by MIMS April 2015

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This leaflet was prepared May 2012.