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Patient Information
Albuterol Sulfate (al bué' ter ol) (sul'fate)
Inhalation Aerosol

Read this Patient Information before you start using albuterol sulfate inhalation aerosol and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is albuterol sulfate inhalation aerosol?

Albuterol sulfate inhalation aerosol is a prescription medicine used in people 4 years of age and older to:

- treat or prevent bronchospasm in people who have reversible obstructive airway disease
- prevent exercise induced bronchospasm

It is not known if albuterol sulfate inhalation aerosol is safe and effective in children under 4 years of age.

Who should not use albuterol sulfate inhalation aerosol?

Do not use albuterol sulfate inhalation aerosol if you are allergic to albuterol sulfate or any of the ingredients in albuterol sulfate inhalation aerosol. See the end of this leaflet for a complete list of ingredients in albuterol sulfate inhalation aerosol.

What should I tell my doctor before I use albuterol sulfate inhalation aerosol?

Before you use albuterol sulfate inhalation aerosol, tell your doctor if you:

- have heart problems
- have high blood pressure (hypertension)
- have convulsions (seizures)
- have thyroid problems
- have diabetes
- have low potassium levels in your blood
- are pregnant or plan to become pregnant. It is not known if albuterol sulfate inhalation aerosol will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if albuterol sulfate passes into your breast milk. Talk to your doctor about the best way to feed your baby if you are using albuterol sulfate inhalation aerosol.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Albuterol sulfate inhalation aerosol and other medicines may affect each other and cause side effects. Albuterol sulfate inhalation aerosol may affect the way other medicines work, and other medicines may affect the way albuterol sulfate inhalation aerosol works.

Especially tell your doctor if you take:

- other inhaled medicines or asthma medicines

- beta blocker medicines
- diuretics
- digoxin
- monoamine oxidase inhibitors
- tricyclic antidepressants

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use albuterol sulfate inhalation aerosol?

- For detailed instructions, see “**Instructions for Use**” at the end of this Patient Information.
- Use albuterol sulfate inhalation aerosol exactly as your doctor tells you to use it.
- If your child needs to use albuterol sulfate inhalation aerosol, watch your child closely to make sure your child uses the inhaler correctly. Your doctor will show you how your child should use albuterol sulfate inhalation aerosol.
- Each dose of albuterol sulfate inhalation aerosol should last up to 4 hours to 6 hours.
- **Do not** increase your dose or take extra doses of albuterol sulfate inhalation aerosol without first talking to your doctor.
- Get medical help right away if albuterol sulfate inhalation aerosol no longer helps your symptoms.
- Get medical help right away if your symptoms get worse or if you need to use your inhaler more often.
- While you are using albuterol sulfate inhalation aerosol, **do not** use other inhaled rescue medicines and asthma medicines unless your doctor tells you to do so.
- Call your doctor if your asthma symptoms like wheezing and trouble breathing become worse over a few hours or days. Your doctor may need to give you another medicine (for example, corticosteroids) to treat your symptoms.

What are the possible side effects of albuterol sulfate inhalation aerosol?

Albuterol sulfate inhalation aerosol may cause serious side effects, including:

- **worsening trouble breathing, coughing and wheezing (paradoxical bronchospasm).** If this happens stop using albuterol sulfate inhalation aerosol and call your doctor or get emergency help right away. Paradoxical bronchospasm is more likely to happen with your first use of a new canister of medicine.
- **heart problems including faster heart rate and higher blood pressure**
- **possible death in people with asthma who use too much albuterol sulfate inhalation aerosol**
- **allergic reactions.** Call your doctor right away if you have the following symptoms of an allergic reaction:
 - itchy skin
 - swelling beneath your skin or in your throat
 - rash
 - worsening trouble breathing
- **low potassium levels in your blood**

- **worsening of other medical problems in people who also use albuterol sulfate inhalation aerosol including increases in blood sugar**

The most common side effects of albuterol sulfate inhalation aerosol include:

- your heart feels like it is pounding or racing (palpitations)
- chest pain
- fast heart rate
- shakiness
- nervousness
- headache
- dizziness
- sore throat
- runny nose

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of albuterol sulfate inhalation aerosol. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store albuterol sulfate inhalation aerosol?

- Store albuterol sulfate inhalation aerosol at room temperature between 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.]
- Avoid exposure to extreme heat and cold.
- Shake the albuterol sulfate inhalation aerosol canister well before use.
- **Do not** puncture the albuterol sulfate inhalation aerosol canister.
- **Do not** store the albuterol sulfate inhalation aerosol canister near heat or a flame. Temperatures above 120° F may cause the canister to burst.
- **Do not** throw the albuterol sulfate inhalation aerosol canister into a fire or an incinerator.
- Avoid spraying albuterol sulfate inhalation aerosol in your eyes.

Keep albuterol sulfate inhalation aerosol and all medicines out of the reach of children.

General Information about the safe and effective use of albuterol sulfate inhalation aerosol

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use albuterol sulfate inhalation aerosol for a condition for which it was not prescribed. Do not give albuterol sulfate inhalation aerosol to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information summarizes the most important information about albuterol sulfate inhalation aerosol. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about albuterol sulfate inhalation aerosol that is written for health professionals.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Instructions for Use
Albuterol Sulfate (al bue'ter ol) (sul' fate)
Inhalation Aerosol

Read this Instructions for Use before you start using albuterol sulfate inhalation aerosol and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

The Parts of Your Albuterol Sulfate inhalation aerosol Inhaler Device:

There are 2 main parts of your albuterol sulfate inhalation aerosol inhaler device including a:

- blue plastic actuator that sprays the medicine from the canister. See Figure A.
- protective green color dust cap that covers the mouthpiece of the actuator. See Figure A.

There is also a metal canister that holds the medicine. See Figure A.

There is also a dose indicator attached around the valve sitting of the actuator with a viewing window that shows you approximately how many sprays of medicine you have left. See Figure B.

You will see the number “200” in the dose indicator window on the actuator. See Figure B. The dose indicator will show the approximate number of actuations (sprays) of medicine remaining in the inhaler. Before you use the inhaler you will need to prime it first. See “**Priming Your Albuterol Sulfate Inhalation Aerosol Device**” below.

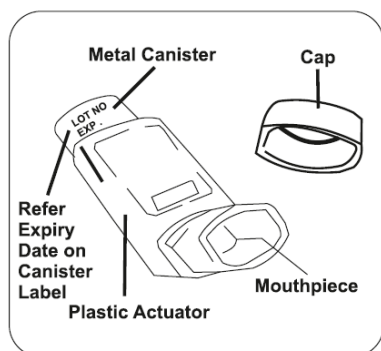


Figure A

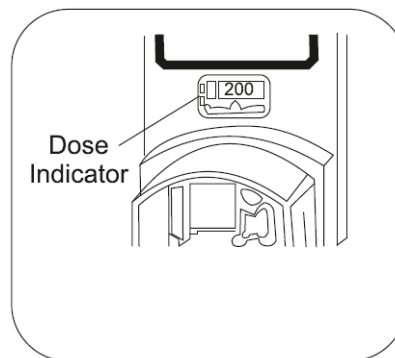


Figure B

- **Do not** use the albuterol sulfate inhalation aerosol actuator with a canister of medicine from any other inhaler.
- **Do not** use an albuterol sulfate inhalation aerosol canister with an actuator from any other inhaler, including another albuterol sulfate inhalation aerosol inhaler.

Priming Your Albuterol Sulfate Inhalation Aerosol Device:

Your albuterol sulfate inhalation aerosol device must be primed before you use it for the first time or if your device has not been used for more than 14 days in a row. **Do not** prime your albuterol sulfate inhalation aerosol device every day.

- Remove your albuterol sulfate inhalation aerosol device from its package.
- Remove the protective dust cap from the mouthpiece.
- Shake the inhaler well, and spray it into the air away from your face. See Figure C.

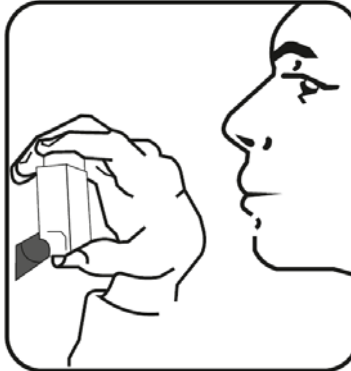


Figure C

- Shake and spray the inhaler like this 2 more times to finish priming it. The dose indicator on the actuator should show the number “200” after you prime the inhaler for the first time. See Figure D.

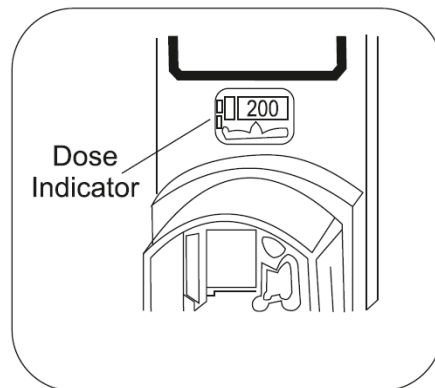


Figure D

Each Time You Use Your Albuterol Sulfate Inhalation Aerosol Device:

- Make sure the canister fits firmly in the plastic actuator.
- Look into the mouthpiece to make sure there are no foreign objects there, especially if the cap has not been used to cover the mouthpiece.

Reading the Dose Indicator on Your Albuterol Sulfate Inhalation Aerosol Actuator:

- The dose indicator will count down each time a spray is released. The dose-indicator window will show the number of sprays left in the inhaler in units of 20 sprays. For example, during every 5 to 7 sprays the dose indicator will count down by 20 towards the next decreasing number. See Figure E.
- When the dose indicator reaches “0”, it will stop moving. Throw away (discard) the inhaler when the dose indicator shows “0” and replace your Albuterol Sulfate Inhalation Aerosol device.
- The dose indicator cannot be reset and is permanently attached to the actuator. **Do not** change the numbers for the dose indicator.
- **Do not** remove the canister from the plastic actuator except during cleaning. Reattaching the

canister to the actuator may accidentally release a dose of albuterol sulfate inhalation aerosol into the air.



Figure E

Using Your Albuterol Sulfate Inhalation Aerosol Device:

Step 1. **Shake the inhaler well** before each spray. Take the cap off the mouthpiece of the actuator.

Step 2. Hold the inhaler with the mouthpiece down. See Figure F.

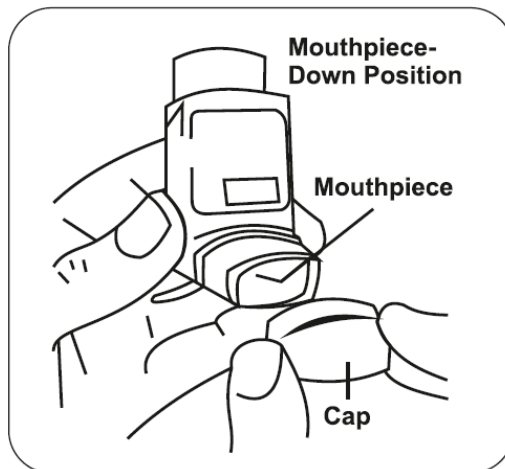


Figure F

Step 3. **Breathe out through your mouth** and push as much air from your lungs as you can. Put the mouthpiece in your mouth and close your lips around it. See Figure G.

Step 4. **Push the top of the canister all the way down while you breathe in deeply and slowly through your mouth.** See Figure G.



Figure G

Step 5. Right after the spray comes out, take your finger off the canister. After you have breathed in all the way, take the inhaler out of your mouth and close your mouth.

Step 6. **Hold your breath as long as you can**, up to 10 seconds, then breathe normally.

If your doctor has told you to use more sprays, wait 1 minute and shake the inhaler again. Repeat Steps 2 through Step 6.

Step 7. Put the cap back on the mouthpiece after every time you use the inhaler. Make sure the cap snaps firmly into place.

Cleaning Your Albuterol Sulfate Inhalation Aerosol Device:

It is very important to keep the plastic actuator clean so the medicine will not build-up and block the spray. See Figure H and Figure I.

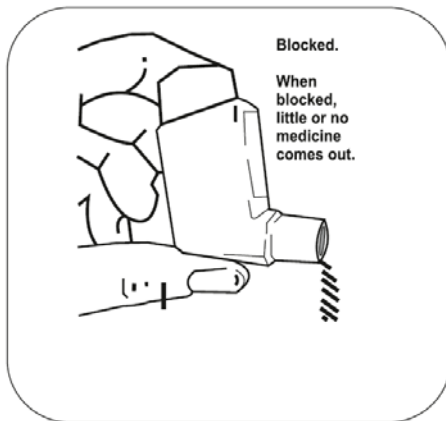


Figure H

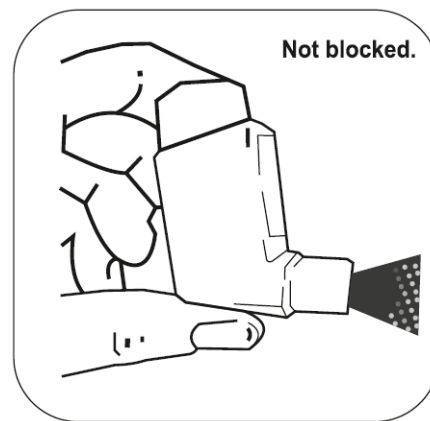


Figure I

- **Do not try to clean the metal canister or let it get wet.** The inhaler may stop spraying if it is not cleaned correctly.
- If you have more than 1 albuterol sulfate inhalation aerosol inhaler, wash each device at separate times to prevent putting the wrong canister together with the wrong plastic actuator. This way you can be sure you will always know the correct number of remaining doses of albuterol sulfate inhalation aerosol.
- **Wash the actuator** at least 1 time each week as follows:
 - Take the canister out of the actuator, and take the cap off the mouthpiece.
 - Hold the actuator under the faucet and run warm water through it for about 30 seconds. See Figure J.

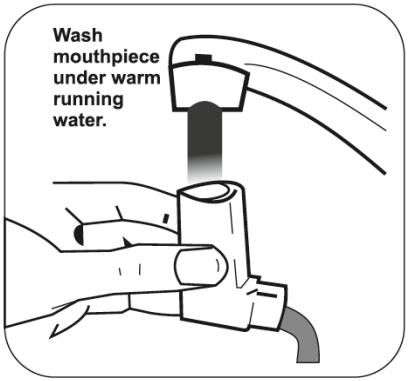


Figure J

- Turn the actuator upside down and run warm water through the mouthpiece for about 30 seconds. See Figure K.

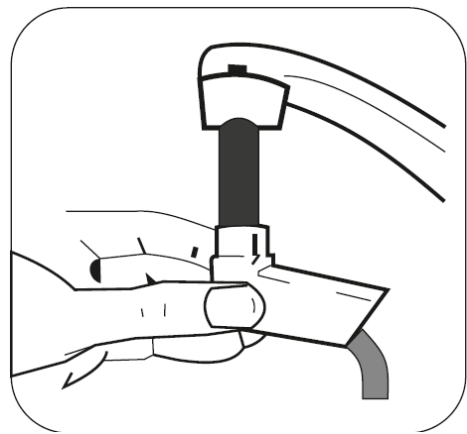


Figure K

- Shake off as much water from the actuator as you can. Look into the mouthpiece to make sure any medicine build-up has been completely washed away. If there is any build-up, repeat the washing instructions.
- Let the actuator air-dry completely, such as overnight. See Figure L.

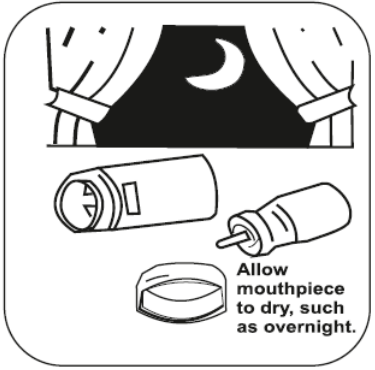


Figure L

- When the actuator is dry, put the canister in the actuator and make sure it fits firmly. Shake the inhaler well and spray it twice into the air away from your face. Put the cap back on the mouthpiece.

If you need to use your inhaler before the actuator is completely dry:

- Shake as much water off the actuator as you can.
- Put the canister in the actuator and make sure it fits firmly.
- Shake the inhaler well and spray it twice into the air away from your face.
- Take your albuterol sulfate inhalation aerosol dose as prescribed.
- Follow the Cleaning Instructions above.

Replacing Your Albuterol Sulfate Inhalation Aerosol Device

- **There are approximately 40 sprays** left when the dose indicator shows the number “40,” and the background color changes from white to red. See Figure M.
 - The red background will remind you to refill your prescription or ask your doctor for another prescription for albuterol sulfate inhalation aerosol.
 - The background color will be all red when the dose indicator approaches “20”.
 - The dose indicator will stop moving at “0”. Throw away (discard) the inhaler once the dose indicator displays “0” See Figure N.

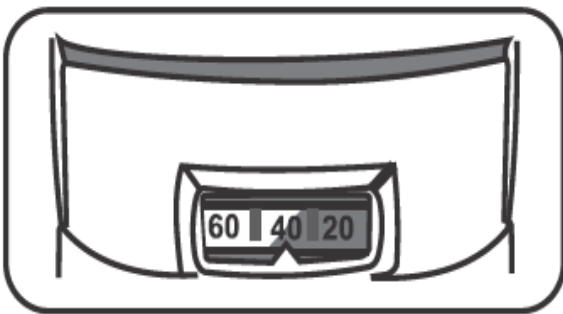


Figure M

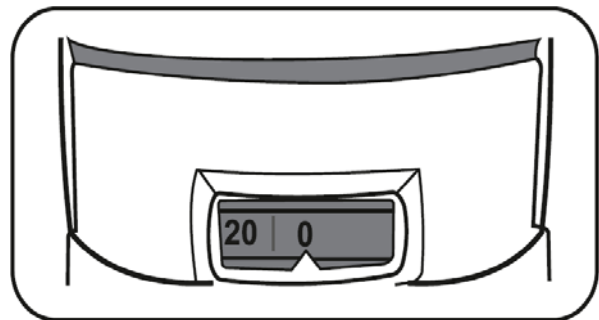



Figure N

- **Throw the albuterol sulfate inhalation aerosol inhaler away** as soon as the dose indicator says “0” or after the expiration date on the albuterol sulfate inhalation aerosol packaging, whichever comes first. You should not keep using the inhaler after 200 sprays even though the canister may not be completely empty. You cannot be sure you will receive any medicine in each actuation (spray) once the dose indicator displays “0”.
- **Do not use the inhaler** after the expiration date on the albuterol sulfate inhalation aerosol packaging.

For more information about Albuterol Sulfate Inhalation Aerosol Device go to <https://lupin.com/albuterol> or call Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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