

MEDICATION GUIDE
BEVESPI AEROSPHERE™
(be-VES-pee AIR-oh-sfeer)
(glycopyrrolate and formoterol fumarate)
inhalation aerosol, for oral inhalation use

What is the most important information I should know about BEVESPI AEROSPHERE?

BEVESPI AEROSPHERE is only approved for use in chronic obstructive pulmonary disease (COPD). BEVESPI AEROSPHERE is NOT approved for use in asthma.

BEVESPI AEROSPHERE can cause serious side effects, including:

- **People with asthma who take long-acting beta₂adrenergic agonist (LABA) medicines, such as formoterol fumarate (one of the medicines in BEVESPI AEROSPHERE), have an increased risk of death from asthma problems.**
- **It is not known if LABA medicines, such as formoterol fumarate (one of the medicines in BEVESPI AEROSPHERE), increase the risk of death in people with COPD.**
- **Call your healthcare provider if breathing problems worsen over time while using BEVESPI AEROSPHERE.** You may need different treatment.
- **Get emergency medical care if:**
 - your breathing problems worsen quickly
 - you use your rescue inhaler, but it does not relieve your breathing problems

What is BEVESPI AEROSPHERE?

BEVESPI AEROSPHERE combines an anticholinergic, glycopyrrolate, and a LABA medicine, formoterol fumarate.

- Anticholinergic and LABA medicines help the muscles around the airways in your lungs stay relaxed to prevent symptoms such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.
- BEVESPI AEROSPHERE is a prescription medicine used to treat COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both.
- BEVESPI AEROSPHERE is used long term as 2 inhalations, 2 times each day in the morning and in the evening, to improve symptoms of COPD for better breathing.
- **BEVESPI AEROSPHERE is not for use to treat sudden symptoms of COPD.** Always have a rescue inhaler (an inhaled, short-acting bronchodilator) with you to treat sudden symptoms. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.
- **BEVESPI AEROSPHERE is not for the treatment of asthma.** It is not known if BEVESPI AEROSPHERE is safe and effective in people with asthma.
- BEVESPI AEROSPHERE should not be used in children. It is not known if BEVESPI AEROSPHERE is safe and effective in children.

Who should not use BEVESPI AEROSPHERE?

Do not use BEVESPI AEROSPHERE if you:

- are allergic to glycopyrrolate, formoterol fumarate, or to any of the ingredients in BEVESPI AEROSPHERE. See **“What are the ingredients in BEVESPI AEROSPHERE?”** below for a complete list of ingredients.
- have asthma. See **“What is the most important information I should know about BEVESPI AEROSPHERE?”**

What should I tell my healthcare provider before using BEVESPI AEROSPHERE?

Before using BEVESPI AEROSPHERE, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- have liver problems
- have eye problems such as glaucoma. BEVESPI AEROSPHERE may make your glaucoma worse.
- have prostate or bladder problems, or problems passing urine. BEVESPI AEROSPHERE may make these problems worse.
- are allergic to any other medicines or food products
- have any other medical conditions
- are pregnant or planning to become pregnant. It is not known if BEVESPI AEROSPHERE may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in BEVESPI AEROSPHERE pass into your breast milk and if they can harm your baby.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter

medicines, vitamins, and herbal supplements. BEVESPI AEROSPHERE and certain other medicines may interact with each other. This may cause serious side effects.

Especially tell your healthcare provider if you take:

- anticholinergics (including tiotropium, ipratropium, aclidinium, and umeclidinium)
- other LABAs (including salmeterol, arformoterol, vilanterol, olodaterol, and indacaterol)
- atropine

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use BEVESPI AEROSPHERE?

Read the step-by-step instructions for using BEVESPI AEROSPHERE at the end of this Medication Guide.

- **Do not** use BEVESPI AEROSPHERE unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
- Use BEVESPI AEROSPHERE exactly as your healthcare provider tells you to use it. **Do not** use BEVESPI AEROSPHERE more often than prescribed.
- Use 2 inhalations of BEVESPI AEROSPHERE, 2 times each day (in the morning and in the evening).
- If you miss a dose of BEVESPI AEROSPHERE, take your next dose at the same time you normally do. **Do not** take more than your prescribed dose of BEVESPI AEROSPHERE.
- **Do not** spray BEVESPI AEROSPHERE in your eyes. If BEVESPI AEROSPHERE gets in your eyes, rinse them well with water. If redness continues, call your healthcare provider.
- **Do not** stop using BEVESPI AEROSPHERE unless told to do so by your healthcare provider because your symptoms might come back. Your healthcare provider will change your medicines as needed.
- **Do not use other medicines that contain a LABA or an anticholinergic for any reason.** Ask your healthcare provider or pharmacist if any of your other medicines are LABA or anticholinergic containing medicines.
- **BEVESPI AEROSPHERE does not relieve sudden symptoms.** Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.
- **Call your healthcare provider or get medical care right away if:**
 - your breathing problems get worse
 - you need to use your rescue inhaler more often than usual
 - your rescue inhaler does not work as well to relieve your symptoms

What are the possible side effects with BEVESPI AEROSPHERE?

BEVESPI AEROSPHERE can cause serious side effects, including:

- **See “What is the most important information I should know about BEVESPI AEROSPHERE?”**
- **sudden breathing problems immediately after inhaling your medicine**
- **serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following symptoms of a serious allergic reaction:
 - rash
 - hives
 - swelling of the face, mouth, and tongue
 - breathing problems
- **effects on your heart:**
 - increase blood pressure
 - a fast or irregular heartbeat
 - chest pain
- **effects on your nervous system:**
 - tremor
 - nervousness
- **new or worsened eye problems including acute narrow-angle glaucoma.** Acute narrow-angle glaucoma can cause permanent loss of vision if not treated. Symptoms of acute narrow-angle glaucoma may include:
 - eye pain or discomfort
 - nausea or vomiting
 - blurred vision
 - seeing halos or bright colors around lights
 - red eyes

If you have these symptoms, call your healthcare provider right away before taking another dose.

- **urinary retention.** People who take BEVESPI AEROSPHERE may develop new or worse urinary retention.

Symptoms of urinary retention may include:

- difficulty urinating
- painful urination
- urinating frequently
- urination in a weak stream or drips

If you have these symptoms of urinary retention, stop taking BEVESPI AEROSPHERE and call your healthcare provider right away before taking another dose.

- **changes in laboratory blood levels,** including high levels of blood sugar (hyperglycemia) and low levels of potassium (hypokalemia) which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm.

Common side effects of BEVESPI AEROSPHERE include:

- urinary tract infection
- cough

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects of BEVESPI AEROSPHERE. Ask your healthcare provider or pharmacist for more information.

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

You may also report side effects to AstraZeneca at 1-800-236-9933.

How do I store BEVESPI AEROSPHERE?

- Store BEVESPI AEROSPHERE at room temperature between 68°F to 77°F (20°C to 25°C).
- **Do not** put a hole in the BEVESPI AEROSPHERE canister.
- **Do not** use or store BEVESPI AEROSPHERE near heat or a flame. Temperatures above 120°F (49°C) may cause the canister to burst.
- **Do not** throw the BEVESPI AEROSPHERE canister into a fire or an incinerator.
- Throw away BEVESPI AEROSPHERE 3 months after you open the foil pouch or when the dose indicator reaches zero "0", whichever comes first.
- **Keep BEVESPI AEROSPHERE and all medicines out of the reach of children.**

General Information about the safe and effective use of BEVESPI AEROSPHERE

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

This Medication Guide summarizes the most important information about BEVESPI AEROSPHERE. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for information about BEVESPI AEROSPHERE that was written for healthcare professionals.

For more information, call 1-800-236-9933 or go to www.BEVESPI.com.

What are the ingredients in BEVESPI AEROSPHERE?

Active ingredients: micronized glycopyrrolate and micronized formoterol fumarate

Inactive ingredients: hydrofluoroalkane (HFA 134a) and porous particles (comprised of DSPC [1,2-Distearoyl-*sn*-glycero-3-phosphocholine] and calcium chloride)

Manufactured for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850; Manufactured by: Aventis Pharma LTD, Holmes Chapel CW48BE, United Kingdom

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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