

## PATIENT INFORMATION

### STIOLTO® RESPIMAT® (sti-OL-to- RES peh mat)

(tiotropium bromide and olodaterol inhalation spray), for oral inhalation use

#### What is STIOLTO RESPIMAT?

- STIOLTO RESPIMAT combines an anticholinergic, tiotropium bromide and a long-acting beta<sub>2</sub>-adrenergic agonist (LABA) medicine, olodaterol.
- Anticholinergic and LABA medicines such as STIOLTO RESPIMAT 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.
- STIOLTO RESPIMAT is a prescription medicine used to control the symptoms of COPD in adults with COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both.
- STIOLTO RESPIMAT is for long-term use and should be taken as 2 puffs 1 time each day, to improve the symptoms of COPD for better breathing.
- **STIOLTO RESPIMAT is not used to treat sudden symptoms of COPD.** Always have a beta<sub>2</sub>-agonist inhaler medicine (rescue inhaler) with you to treat sudden symptoms of COPD. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.
- **STIOLTO RESPIMAT is not for the treatment of asthma. It is not known if STIOLTO RESPIMAT is safe and effective in people with asthma.**
- **STIOLTO RESPIMAT should not be used in children. It is not known if STIOLTO RESPIMAT is safe and effective in children.**

#### Do not use STIOLTO RESPIMAT if you:

- have asthma.
- are allergic to tiotropium, ipratropium, olodaterol, or any of the ingredients in STIOLTO RESPIMAT. See the end of this Patient Information leaflet for a complete list of ingredients in STIOLTO RESPIMAT.

#### Before you use STIOLTO RESPIMAT, 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 eye problems, such as glaucoma. STIOLTO RESPIMAT can make your glaucoma worse.
- have prostate or bladder problems, or problems passing urine. STIOLTO RESPIMAT can make these problems worse.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if the medicines tiotropium or olodaterol in STIOLTO RESPIMAT can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if the medicines tiotropium or olodaterol in STIOLTO RESPIMAT passes into your breast milk and if it can harm your baby. You and your healthcare provider should decide if you will take STIOLTO RESPIMAT while breastfeeding.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, eye drops, vitamins, and herbal supplements. STIOLTO RESPIMAT and certain other medicines may affect each other. This may cause serious side effects.

Especially tell your healthcare provider if you take:

- anticholinergics (including ipratropium, aclidinium, umeclidinium or another tiotropium-containing product such as SPIRIVA RESPIMAT or SPIRIVA HANDIHALER)
- atropine

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

#### How should I use STIOLTO RESPIMAT?

**Read the step-by-step instructions for using STIOLTO RESPIMAT at the end of this Patient Information leaflet.**

- **Do not** use STIOLTO RESPIMAT unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly. Ask your healthcare provider or pharmacist if you have any questions.
- STIOLTO RESPIMAT inhaler has a slow-moving mist that helps you inhale the medicine.
- Use STIOLTO RESPIMAT exactly as your healthcare provider tells you to use it. **Do not use STIOLTO RESPIMAT more often than prescribed.**
- **Use 1 dose (2 puffs) of STIOLTO RESPIMAT, 1 time each day, at the same time of the day.**
- If you miss a dose of STIOLTO RESPIMAT, take it as soon as you remember. Do not take more than 1 dose (2 puffs) in 24 hours.

- **If you take too much STIOLTO RESPIMAT, call your healthcare provider or go to the nearest hospital emergency room right away.**
- **Do not spray STIOLTO RESPIMAT in your eyes.** Your vision may become blurred and your pupils may become larger (dilated).
- STIOLTO RESPIMAT Inhalation Spray should only be given using the STIOLTO RESPIMAT inhaler. The STIOLTO RESPIMAT inhaler should not be used to give other medicines.
- Always use the new STIOLTO RESPIMAT inhaler that is provided with each new prescription.
- **STIOLTO RESPIMAT does not relieve sudden symptoms of COPD. You should not take extra doses of STIOLTO RESPIMAT to relieve sudden symptoms of COPD.** Always have a rescue inhaler medicine with you to treat sudden symptoms. If you do not have a rescue inhaler medicine, call your healthcare provider to have one prescribed for you.
- If your COPD symptoms worsen over time, do not increase your dose of STIOLTO RESPIMAT, instead call your healthcare provider.
- **Do not stop using STIOLTO RESPIMAT or other medicines to control or treat your COPD unless told to do so by your healthcare provider because your symptoms might get worse.** Your healthcare provider will change your medicines as needed.
- **Do not use STIOLTO RESPIMAT:**
  - more often than prescribed for you,
  - at a higher dose than prescribed for you, or
  - with other medicines that contain LABA or an anticholinergic for any reason. Ask your healthcare provider or pharmacist if any of your other medicines are LABA or anticholinergic medicines.
- **Call your healthcare provider or get emergency medical care right away if your breathing problems worsen with STIOLTO RESPIMAT, you need to use your rescue inhaler medicine more often than usual, or your rescue inhaler medicine does not work as well for you at relieving your symptoms.**

#### **What are the possible side effects with STIOLTO RESPIMAT?**

##### **STIOLTO RESPIMAT can cause serious side effects, including:**

- **serious problems from asthma.** People with asthma who take long-acting beta<sub>2</sub>-adrenergic agonist (LABA) medicines, such as olodaterol (one of the medicines in STIOLTO RESPIMAT), without also using a medicine called an inhaled corticosteroid, have an increased risk of serious problems from asthma, including being hospitalized, needing a tube placed in their airway to help them breathe, or death.
- **call your healthcare provider if breathing problems worsen over time while using STIOLTO RESPIMAT.** You may need a different treatment.  
**Get emergency medical care if:**
  - your breathing problems worsen quickly
  - you use your rescue inhaler medicine, but it does not relieve your breathing problems
- **using too much of a LABA medicine (one of the medicines in STIOLTO RESPIMAT) may cause:**

○ chest pain	○ increased blood pressure
○ fast and irregular heartbeat	○ headache
○ tremor	○ nervousness
- **COPD symptoms can get worse over time.** If your COPD symptoms worsen over time, do not increase your dose of STIOLTO RESPIMAT, instead call your healthcare provider.
- **serious allergic reactions including rash, hives, itching, swelling of the face, lips, tongue, throat, difficulties in breathing or swallowing.** Stop taking STIOLTO RESPIMAT and get emergency medical help right away if you get any symptoms of a serious allergic reaction after using STIOLTO RESPIMAT.
- **sudden shortness of breath can happen immediately after using STIOLTO RESPIMAT.** Sudden shortness of breath may be life-threatening. Stop taking STIOLTO RESPIMAT and call your healthcare provider or get emergency medical help right away if you get sudden shortness of breath after using STIOLTO RESPIMAT.
- **effects on your heart,** including fast or irregular heartbeat, palpitations, chest pain, and increased blood pressure.
- **new or worsening eye problems including acute narrow-angle glaucoma.** Symptoms of acute narrow-angle glaucoma include eye pain or discomfort, blurred vision, seeing halos or colored images around lights, and red eyes. Call your healthcare provider right away if you have any of these symptoms. Use caution as some of these eye problems can affect your ability to drive and operate appliances and machinery.
- **new or worsening urinary retention.** Symptoms of urinary retention may include difficulty urinating, painful urination, urinating frequently, or urinating in a weak stream or drips. Call your healthcare provider right away if you have any of these symptoms.
- **changes in laboratory blood levels including high blood sugar (hyperglycemia) and low levels of potassium (hypokalemia), which** may cause symptoms of muscle weakness or abnormal heart rhythm.

**Common side effects of STIOLTO RESPIMAT include** runny nose, cough, and back pain.

These are not all the side effects of STIOLTO RESPIMAT. 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 STIOLTO RESPIMAT?**

- Store STIOLTO RESPIMAT at room temperature, between 68°F to 77°F (20°C to 25°C).
- **Do not** freeze your STIOLTO cartridge or RESPIMAT inhaler.
- **Keep your STIOLTO RESPIMAT inhaler, cartridge, and all medicines out of the reach of children.**

**General information about the safe and effective use of STIOLTO RESPIMAT**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use STIOLTO RESPIMAT for a condition for which it was not prescribed. Do not give STIOLTO RESPIMAT to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about STIOLTO RESPIMAT that is written for health professionals.

**Active ingredients:** Tiotropium bromide and olodaterol

**Inactive ingredients:** water for injection, benzalkonium chloride, edetate disodium, and hydrochloric acid

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Boehringer Ingelheim Pharmaceuticals, Inc.  
Ridgefield, CT 06877 USA

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IT6053OG232020

For more information about STIOLTO RESPIMAT, including current prescribing information, a video demonstration or a Quick Start Guide on how to use STIOLTO RESPIMAT, go to [www.STIOLTO.com](http://www.STIOLTO.com), scan the code below, or call 1-800-542-6257 or (TTY) 1-800-459-9906.

