

Medication Guide
STIOLTO® RESPIMAT® (sti-OL-to- RES peh mat)
(tiotropium bromide and olodaterol) Inhalation Spray

Read the Medication Guide that comes with STIOLTO RESPIMAT before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about STIOLTO RESPIMAT?

STIOLTO RESPIMAT has been approved for chronic obstructive pulmonary disease (COPD) only. STIOLTO RESPIMAT is not to be used in asthma.

STIOLTO RESPIMAT can cause serious side effects, including:

- **People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines, such as olodaterol (one of the medicines in STIOLTO RESPIMAT), have an increased risk of death from asthma problems.**
- **It is not known if LABA medicines, such as olodaterol (one of the medicines in STIOLTO RESPIMAT), increase the risk of death in people with COPD.**
- Get emergency medical care if:
 - breathing problems worsen quickly
 - you use your rescue inhaler medicine, but it does not relieve your breathing problems

What is STIOLTO RESPIMAT?

STIOLTO RESPIMAT contains the anticholinergic tiotropium, and the long-acting beta₂-adrenergic agonist (LABA), olodaterol.

STIOLTO RESPIMAT is used long term, 2 puffs once each day, in controlling symptoms of COPD in adults with COPD.

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.

STIOLTO RESPIMAT is not for use to treat sudden symptoms of COPD. Always have a rescue medicine with you to treat sudden symptoms. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.

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.

Who should not use STIOLTO RESPIMAT?

Do not use STIOLTO RESPIMAT if:

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

What should I tell my healthcare provider before using STIOLTO RESPIMAT?

Tell your healthcare provider about all of your health 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 any other medical conditions
- are pregnant or planning to become pregnant. It is not known if STIOLTO RESPIMAT can harm your unborn baby.
- are breastfeeding. It is not known if STIOLTO RESPIMAT passes into your breast milk and if it can harm your baby.
- are allergic to STIOLTO RESPIMAT or any of its ingredients, any other medicines, or food products.

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 interact with 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 Medication Guide.
- 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.
- **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.
- **Do not spray STIOLTO RESPIMAT in your eyes.**
- Always use the new STIOLTO RESPIMAT inhaler that is provided with each new prescription.

- **STIOLTO RESPIMAT does not 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.
- 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, 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 medicine more often than usual
 - 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:

- **See “What is the most important information I should know about STIOLTO RESPIMAT?”**
- If your COPD symptoms worsen over time do not increase your dose of STIOLTO RESPIMAT, instead call your healthcare provider.
- sudden shortness of breath that may be life-threatening
- serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue, and breathing problems. Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction.
- heart problems including fast or irregular heartbeat, palpitations, chest pain, 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.
- low blood potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm)
- high blood sugar

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

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

These are not all the side effects with STIOLTO RESPIMAT. 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.

How should I store STIOLTO RESPIMAT?

- Store STIOLTO RESPIMAT at room temperature 68°F to 77°F (20°C to 25°C).
- Do not freeze your STIOLTO cartridge or RESPIMAT inhaler.
- **Keep your STIOLTO RESPIMAT 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 Medication Guide. 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 condition. It may harm them.

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

For more information about STIOLTO RESPIMAT or a video demonstration on how to use STIOLTO RESPIMAT, go to www.STIOLTO.com, or scan the code below. You may also call 1-800-542-6257 or (TTY) 1-800-459-9906 for further information about STIOLTO RESPIMAT.



What are the ingredients in STIOLTO RESPIMAT?

Active ingredients: Tiotropium bromide and olodaterol

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

Instructions for Use
STIOLTO[®] RESPIMAT[®]
(sti-OL-to- RES peh mat)
(tiotropium bromide and olodaterol)
inhalation spray

For Oral Inhalation Only

Do not spray STIOLTO RESPIMAT into your eyes.

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

You will need to use this inhaler ONCE A DAY, at the same time each day. Each time you use it take TWO PUFFS.

Do not turn the clear base before inserting the cartridge.



How to store your STIOLTO RESPIMAT inhaler

- Store STIOLTO RESPIMAT at room temperature 68°F to 77°F (20°C to 25°C).
- Do not freeze your STIOLTO RESPIMAT cartridge and inhaler.
- If STIOLTO RESPIMAT has not been used for more than 3 days, release 1 puff towards the ground.
- If STIOLTO RESPIMAT has not been used for more than 21 days, repeat steps 4 to 6 under the "Prepare for first use" until a mist is visible. Then repeat steps 4 to 6 three more times.
- Keep your STIOLTO RESPIMAT cartridge and inhaler out of the reach of children.

How to care for your STIOLTO RESPIMAT inhaler

Clean the mouthpiece, including the metal part inside the mouthpiece, with a damp cloth or tissue only, at least once a week. Any minor discoloration in the mouthpiece does not affect your STIOLTO RESPIMAT inhaler.

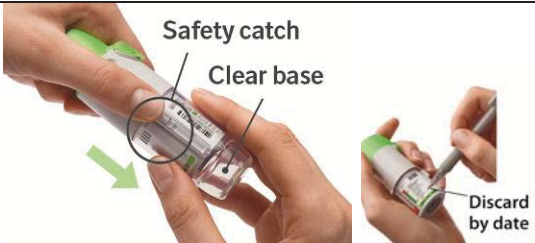


When to get a new STIOLTO RESPIMAT inhaler



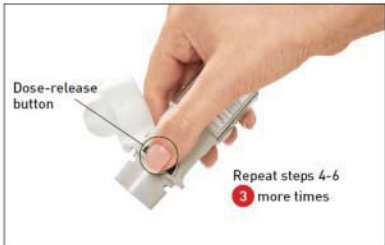
- Your inhaler contains 60 puffs (30 doses) if used as indicated (2 puffs once daily). If you have a sample, your inhaler contains 28 puffs (14 doses) if used as indicated (2 puffs once daily).





- The dose indicator shows approximately how much medicine is left.
- When the dose indicator enters the red area of the scale you need to get a refill; there is approximately medicine for 7 days left (if you have a sample, there is approximately medicine for 3 days left).
- When the dose indicator reaches the end of the red scale, your STIOLTO RESPIMAT is empty and automatically locks. At this point, the clear base cannot be turned any further.
- Three months after insertion of cartridge, throw away the STIOLTO RESPIMAT even if it has not been used, or when the inhaler is locked, or when it expires, whichever comes first.

Prepare for first use

| | |
|---|--|
| <p>1. Remove clear base</p> <ul style="list-style-type: none">Keep the cap closed.Press the safety catch while firmly pulling off the clear base with your other hand. Be careful not to touch the piercing element.Write the discard by date on the label (3 months from the date the cartridge is inserted). |  |
| <p>2. Insert cartridge</p> <ul style="list-style-type: none">Insert the narrow end of the cartridge into the inhaler.Place the inhaler on a firm surface and push down firmly until it clicks into place. |  |
| <p>3. Replace clear base</p> <ul style="list-style-type: none">Put the clear base back into place until it clicks.Do not remove the clear base or the cartridge after it has been put together. |  |

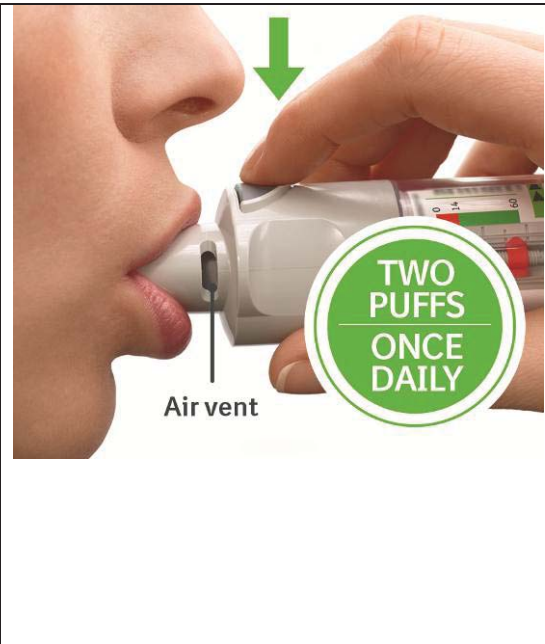
| | |
|---|---|
| <p>4. Turn</p> <ul style="list-style-type: none"> Keep the cap closed. Turn the clear base in the direction of the arrows on the label until it clicks (half a turn). |  |
| <p>5. Open</p> <ul style="list-style-type: none"> Open the cap until it snaps fully open. |  |
| <p>6. Press</p> <ul style="list-style-type: none"> Point the inhaler toward the ground. Press the dose-release button. Close the cap. If you do not see a mist, repeat steps 4 to 6 until a mist is seen. After a mist is seen, repeat steps 4 to 6 three more times. After complete preparation of your inhaler, it will be ready to deliver the number of puffs on the label. |  |

Daily use (I O P)

| | |
|---|--|
| <p><u>I</u> Turn</p> <ul style="list-style-type: none"> Keep the cap closed. Turn the clear base in the direction of the arrows on the label until it clicks (half a turn). |  |
| <p><u>O</u> Open</p> <ul style="list-style-type: none"> Open the cap until it snaps fully open. |  |

Press

- Breathe out slowly and fully.
- Close your lips around the mouthpiece without covering the air vents.
- Point the inhaler to the back of your throat.
- While taking a slow, deep breath through your mouth, **Press** the dose-release button and continue to breathe in.
- Hold your breath for 10 seconds or for as long as comfortable.
- Repeat **Turn, Open, Press (TOP)** for a total of 2 puffs.
- Close the cap until you use your inhaler again.



Answers to Common Questions

It is difficult to insert the cartridge deep enough:

Did you accidentally turn the clear base before inserting the cartridge? Open the cap, press the dose-release button, then insert the cartridge.

Did you insert the cartridge with the wide end first? Insert the cartridge with the narrow end first.

I cannot press the dose-release button:

Did you turn the clear base? If not, turn the clear base in a continuous movement until it clicks (half a turn).

Is the dose indicator on the STIOLTO RESPIMAT is pointing to zero? The STIOLTO RESPIMAT inhaler is locked after 60 puffs (30 doses). If you have a sample, the STIOLTO RESPIMAT inhaler is locked after 28 puffs (14 doses). Prepare and use your new STIOLTO RESPIMAT inhaler.

I cannot turn the clear base:

Did you turn the clear base already? If the clear base has already been turned, follow steps "Open" and "Press" under "Daily use" to get your medicine.

Is the dose indicator on the STIOLTO RESPIMAT pointing zero? The STIOLTO RESPIMAT inhaler is locked after 60 puffs (30 doses). If you have a sample, the STIOLTO RESPIMAT inhaler is locked after 28 puffs (14 doses). Prepare and use your new STIOLTO RESPIMAT inhaler.

The dose indicator on the STIOLTO RESPIMAT reaches zero too soon:

Did you use STIOLTO RESPIMAT as indicated (2 puffs once daily)? STIOLTO RESPIMAT will deliver 60 puffs and last 30 days if used at 2 puffs once daily. If you have a sample, STIOLTO RESPIMAT will deliver 28 puffs and last 14 days if used at 2 puffs once daily.

Did you turn the clear base before you inserted the cartridge? The dose indicator counts each turn of the clear base regardless whether a cartridge has been inserted or not.

Did you spray in the air often to check whether the STIOLTO RESPIMAT is working?

Once you have prepared STIOLTO RESPIMAT no test-spraying is required if used daily.

Did you insert the cartridge into a used STIOLTO RESPIMAT? Always insert a new cartridge into a **NEW** STIOLTO RESPIMAT.

My STIOLTO RESPIMAT sprays automatically:

Was the cap open when you turned the clear base? Close the cap, then turn the clear base.

Did you press the dose-release button when turning the clear base? Close the cap, so the dose-release button is covered, then turn the clear base.

Did you stop when turning the clear base before it clicked? Turn the clear base in a continuous movement until it clicks (half a turn).

My STIOLTO RESPIMAT doesn't spray:

Did you insert a cartridge? If not, insert a cartridge.

Did you repeat Turn, Open, Press (TOP) less than three times after inserting the cartridge? Repeat Turn, Open, Press (TOP) three times after inserting the cartridge as shown in steps 4 to 6 under "Prepare for first use".

Is the dose indicator on the STIOLTO RESPIMAT pointing to 0? You have used up all your medicine and the inhaler is locked.

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

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