

PART III: CONSUMER INFORMATION

PrStriverdi[®] Respimat[®]
Olodaterol Hydrochloride Inhalation Solution

Read this carefully before you start taking STRIVERDI RESPIMAT and each time you get a refill. This leaflet is a summary and will not tell you everything about STRIVERDI RESPIMAT. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about STRIVERDI RESPIMAT.

ABOUT THIS MEDICATION

What the medication is used for:

STRIVERDI RESPIMAT is a long-acting beta₂-adrenergic agonist (LABA) used to make breathing easier for people who experience breathing difficulties due to a lung disease called Chronic Obstructive Pulmonary Disease or COPD (including chronic bronchitis and emphysema).

What it does:

STRIVERDI RESPIMAT helps the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness and shortness of breath.

When it should not be used:

Do not use STRIVERDI RESPIMAT:

- if you have asthma;
- to treat sudden symptoms of COPD;
- if you are less than 18 years of age;
- if you are allergic (hypersensitive) to olodaterol hydrochloride or any of the non-medicinal ingredients in the formulation.

What the medicinal ingredient is:

Olodaterol Hydrochloride

What the non-medicinal ingredients are:

Benzalkonium chloride, citric acid, edetate disodium and purified water.

What dosage forms it comes in:

Inhalation solution: 2.5 mcg per puff

STRIVERDI RESPIMAT is supplied in a carton containing one STRIVERDI RESPIMAT cartridge and one STRIVERDI RESPIMAT inhaler.

The STRIVERDI RESPIMAT cartridge is only intended for use with the STRIVERDI RESPIMAT inhaler.

WARNINGS AND PRECAUTIONS

Warnings – Asthma-Related Death

You are advised that in patients with asthma, long-acting beta₂-agonist (LABA) medicines increase the chance of death from asthma problems. In a large asthma study, more patients who used another LABA medicine (salmeterol) died from asthma problems compared with patients who did not use that LABA medicine. This finding may also apply to STRIVERDI RESPIMAT.

STRIVERDI RESPIMAT should only be used to treat COPD.

STRIVERDI RESPIMAT should not be used to treat asthma.

BEFORE you use STRIVERDI RESPIMAT talk to your doctor, nurse or pharmacist if you:

- have heart problems, such as rapid or irregular heart beat or abnormal electrical signal called “prolongation of the QT interval”;
- have high blood pressure;
- have seizures;
- have thyroid problems;
- have diabetes;
- are taking other LABA drugs;
- have been told you react strongly to sympathomimetic amines (a class of drugs that includes LABA drugs);
- are pregnant or planning to become pregnant. It is not known if STRIVERDI RESPIMAT can harm your unborn baby;
- are breastfeeding. It is not known if STRIVERDI RESPIMAT passes into your milk and if it can harm your baby.

During the treatment with STRIVERDI RESPIMAT, tell your doctor immediately if you experience any of the following symptoms:

- If you experience a tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (signs of bronchospasm).
- If you experience difficulties in breathing or swallowing, swelling of tongue, lips and face, hives or itching, skin rash (signs of hypersensitivity reaction). Do not use STRIVERDI RESPIMAT again before speaking with your doctor.
- If your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen during your treatment.

STRIVERDI RESPIMAT does not relieve sudden symptoms of COPD. Always have a short-acting bronchodilator medicine with you to treat acute symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your healthcare provider to have one prescribed for you.

Get emergency medical care if:

- breathing problems worsen quickly;
- you use your rescue inhaler medicine, but it does not relieve your breathing problems.

Driving and using machines: Caution is required when driving a car or operating machinery as dizziness may occur with the use of STRIVERDI RESPIMAT. If you experience dizziness, you should avoid driving or operating machinery.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with STRIVERDI RESPIMAT:

- antidepressants, in particular tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs);
- medicines similar to STRIVERDI RESPIMAT (other LABA) used for your lung disease as it may increase the risk of experiencing possible side effects;
- medicines that decrease the level of potassium in your blood. These include diuretics (also known as “water pills” and are used to treat high blood pressure e.g. hydrochlorothiazide), other bronchodilators such as methylxanthines (e.g. theophylline) or steroids (e.g. prednisolone);
- beta-blockers used in the treatment of high blood pressure or other heart problems (e.g. propranolol) or in the treatment of glaucoma (e.g. timolol).

PROPER USE OF THIS MEDICATION

- Read the **Instructions for use** before using STRIVERDI RESPIMAT and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor, nurse or pharmacist about your medical condition or your treatment.
- Always use the new STRIVERDI RESPIMAT inhaler that is provided with each new prescription.
- STRIVERDI 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, ask your healthcare provider.
- Do not stop using STRIVERDI 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 STRIVERDI RESPIMAT:**
 - more often than prescribed;
 - with other medicines that contain a long-acting beta₂-agonist (LABA) for any reason.
- Do not spray into eyes.
- Call your healthcare provider or get emergency medical care

right away if:

- your breathing problems worsen with STRIVERDI 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.

Usual Adult Dose:

The recommended dose of STRIVERDI RESPIMAT is 2 puffs (5 mcg olodaterol), once daily at the same time of the day.

The STRIVERDI RESPIMAT inhaler, is designed to deliver 60 puffs after preparation for use; the equivalent of 30 days medication when used according to the directions for use (one dose equals 2 puffs).

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of STRIVERDI RESPIMAT, take it as soon as you remember. Do not take more than one dose (2 puffs) per day. Then take your next dose as usual.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- inflammation of the throat and nasal passages;
- feeling dizzy;
- rash;
- swollen painful joints;
- back pain;
- tremor;
- headache;
- nervousness, feeling anxious;
- difficulty sleeping (insomnia);
- dry mouth;
- pain in mouth and throat;
- nausea;
- muscle spasms;
- muscular pain;
- feeling tired;
- feeling unwell;
- cough;
- diarrhea;
- stomach/digestion problems;
- upper respiratory tract infection (common cold).

If any of these affects you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Bronchitis: shortness of breath, cough, chest pain		√	
	Bladder infection: pain and burning when urinating, frequent urination		√	
Uncommon	Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	Bronchospasm: wheezing or coughing and difficulty breathing			√
	Lower respiratory infection: shortness of breath, cough, chest pain		√	
	High or low blood pressure: headache, ringing in the ears, lightheadedness, dizziness, fainting		√	
	Fast or irregular heartbeat, heart palpitations, prolongation of QT interval		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Myocardial ischaemia (decreased blood flow to your heart muscle): chest pain, trouble breathing, swelling of the hands or feet, heartburn			√
	Chest pain		√	
	Low blood potassium: irregular heartbeats, muscle weakness or spasms and generally feeling unwell		√	
	High blood sugar: frequent urination, thirst, and hunger	√		
	Blood pH imbalance: chest pain, headache, heart palpitations, nausea, vomiting, stomach pain			√
	Swelling of the feet, ankles or legs		√	

This is not a complete list of side effects. For any unexpected effects while taking STRIVERDI RESPIMAT, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store STRIVERDI RESPIMAT between 15–30°C.

Do not freeze your STRIVERDI RESPIMAT cartridge and inhaler.

Keep your STRIVERDI RESPIMAT cartridge and inhaler out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.boehringer-ingenelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

Please visit our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

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INSTRUCTIONS FOR USE

2
PUFFS
ONCE
A DAY

Introduction

Read these **Instructions for Use** before you start using STRIVERDI RESPIMAT.

You will need to use this inhaler only ONCE A DAY. Each time you use it take 2 PUFFS.

Each box contains:

- 1 RESPIMAT inhaler
- 1 cartridge

Each cartridge provides 60 puffs (30 doses).

The colour of the cap of the RESPIMAT inhaler is colour coded to match the cartridge.



How to store my STRIVERDI RESPIMAT inhaler

Store STRIVERDI RESPIMAT (the cartridge and inhaler) between 15-30°C. Do not freeze.

Keep out of the sight and reach of children.

Do not use your inhaler after the expiry date.

Do not touch the piercing element inside the clear base.

If you have not used your inhaler in more than:

- 7 days: release 1 puff towards the ground
- 21 days: repeat steps 4 to 6 under “Prepare for first Use” until a cloud is visible. Then repeat steps 4 to 6 three more times.

How to care for your STRIVERDI RESPIMAT

Clean the mouthpiece including the metal part inside the mouthpiece with a damp cloth or tissue only. You should do this at least once a week. Any minor changes in the colour of the mouthpiece will not affect how your STRIVERDI RESPIMAT works.

When to get a new STRIVERDI RESPIMAT



- Your STRIVERDI RESPIMAT inhaler contains 60 puffs (30 doses) if you use it as directed (2 puffs /once a day).
- The dose indicator shows you about how much medication is left.
- When the dose indicator **enters** the red area of the scale, there is about 7 days of medication left. You need to get a new prescription or refill your prescription.
- Once the dose indicator reaches the **end** of the red scale:
 - Your STRIVERDI RESPIMAT locks automatically. No more doses can be released. At this point, the clear base cannot be turned any further.
- You should throw out STRIVERDI RESPIMAT when one of the following happens first:
 - 3 months after first use, even if all the medication has not been used, or
 - it locks automatically.

Prepare for First Use

1

Remove clear base

- Keep the cap closed.
- Press the safety catch while firmly pulling off the clear base with your other hand.



2

Insert cartridge

- Insert the **narrow** end of the cartridge into the inhaler.
- Place the inhaler on a firm surface and push down firmly until it snaps into place.
- You should hear a “click” when it has gone in all the way.



3

Replace clear base

- Put the clear base back into place until it “clicks”.
- Do not remove the clear base again.



4

Turn

- Keep the cap closed.
- Turn the clear base in the direction of the arrows on the label until it “clicks” (half a turn).



5

Open

- Open the cap until it snaps fully open.



6

Press

- Point the inhaler toward the ground.
- Press the dose-release button.
- Close the cap.
- Repeat steps 4 to 6 **until** a cloud is visible.
- **After a cloud is visible**, repeat steps 4 to 6 three more times.

Your inhaler is now ready to use.



Daily Use

TURN

- Keep the cap closed.
- **TURN** the clear base in the direction of the arrows on the label until it “clicks” (half a turn).



OPEN

- **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.
- 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 you feel comfortable.

To take your second puff, repeat the 3 steps, TURN, OPEN and PRESS (TOP) one more time.

Close the cap.



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.

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

Did you use STRIVERDI RESPIMAT as indicated (2 puffs/once daily)? STRIVERDI RESPIMAT will last 30 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 STRIVERDI RESPIMAT is working? Once you have prepared STRIVERDI RESPIMAT, no test-spraying is required if used daily.

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

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 STRIVERDI RESPIMAT pointing to zero? The STRIVERDI RESPIMAT inhaler is locked after 60 puffs (30 doses). Prepare and use your new STRIVERDI RESPIMAT inhaler.

My STRIVERDI 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 STRIVERDI RESPIMAT pointing to 0? If the dose indicator points to 0, you have used up all your medication and the inhaler is locked.

Once your STRIVERDI RESPIMAT is assembled, do not remove the clear base or the cartridge. Always insert a new cartridge into a **NEW** STRIVERDI RESPIMAT.

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 the directions for "Daily Use" to get your medicine.

Is the dose indicator on the STRIVERDI RESPIMAT pointing to zero? The STRIVERDI RESPIMAT inhaler is locked after 60 puffs (30 doses). Prepare and use your new STRIVERDI RESPIMAT inhaler.

My STRIVERDI 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).