

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Fr OXEZE® TURBUHALER®

formoterol fumarate dihydrate dry powder for oral inhalation

This leaflet is part III of a three-part “Product Monograph” published when OXEZE TURBUHALER was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OXEZE TURBUHALER. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

What the medication is used for:

OXEZE TURBUHALER is used to help breathing problems in patients with asthma and its related conditions **only as an add-on therapy to an inhaled corticosteroid**. Your doctor has prescribed OXEZE TURBUHALER because you or your child’s asthma is not well controlled with current asthma medications (e.g. inhaled glucocorticosteroids along with an as needed short-acting bronchodilator medication). An inhaled glucocorticosteroid must always be used if you or your child is using OXEZE TURBUHALER.

The efficacy and safety of OXEZE TURBUHALER in children younger than 6 years has not been established.

Note to Parents: It is important that you watch your child(ren) to make sure that they take both OXEZE TURBUHALER **and** an inhaled corticosteroid at the same time. If you cannot ensure that your child(ren) is taking **both** medications at the same time, then talk to your doctor. A combination product may be required.

What it does:

When taken regularly with an inhaled corticosteroid, twice daily maintenance treatment with OXEZE TURBUHALER gives 24 hour relief or prevention of symptoms such as shortness of breath in patients with asthma and its related conditions.

Formoterol is a fast-acting bronchodilator with a long duration of action. It widens the airways enabling you to breathe more easily. You usually notice an effect from OXEZE TURBUHALER within 1-3 minutes.

When it should not be used:

OXEZE TURBUHALER should not be used to provide relief for a sudden attack of breathlessness.

Remember:

- Do not take OXEZE TURBUHALER without an inhaled corticosteroid. If you are being treated for asthma, you should always be given both OXEZE TURBUHALER and an inhaled corticosteroid to use together. The inhaled corticosteroid decreases the inflammation in your lungs while OXEZE TURBUHALER opens the airways. A third drug, a relief medication, should be used for any sudden attacks of breathlessness (asthma attacks).
- Do not use OXEZE TURBUHALER if you are allergic to formoterol or inhaled lactose (which may contain milk protein residue).
- Do not use OXEZE TURBUHALER if you have a heart problem called tachyarrhythmia (fast and/or irregular heart beat).

What the medicinal ingredient is:

Formoterol fumarate dihydrate.

What the nonmedicinal ingredients are:

Lactose monohydrate (which may contain milk protein residue).

What dosage forms it comes in:

Dry powder for oral inhalation: 6 mcg and 12 mcg/dose. Each inhaler contains 60 doses.

WARNINGS AND PRECAUTIONS

Serious Warnings for Asthma Patients

OXEZE TURBUHALER may increase the risk of asthma-related death. It may increase the risk of asthma-related hospitalizations in pediatric and adolescent patients.

Therefore,

- OXEZE TURBUHALER must **only** be used as an **add-on** therapy when your inhaled corticosteroid does not adequately control your asthma symptoms.
- OXEZE TURBUHALER must always be used together with an inhaled corticosteroid.
- The dose of OXEZE TURBUHALER may be reduced or discontinued by your doctor when your asthma is assessed as adequately under control (step-down therapy).

For any concerns regarding the use of OXEZE TURBUHALER, consult your doctor.

BEFORE you use OXEZE TURBUHALER talk to your doctor or pharmacist:

- about all health problems you have now or have had in the past, especially if you have a heart disorder, diabetes, or a disturbed thyroid function (thyrotoxicosis);

- if you have ever had a bad, unusual or allergic reaction to formoterol or lactose or to other medicines for breathing problems;
- if you are pregnant, plan to become pregnant or are breast feeding.

When to call your doctor:

If you are using more of your fast-acting bronchodilator medication or if you feel that it is less effective TELL YOUR DOCTOR RIGHT AWAY. Your doctor may adjust your treatment.

If your symptoms are waking you up at night, TELL YOUR DOCTOR RIGHT AWAY. Your doctor may adjust your treatment.

If you have taken all your medication as instructed by your doctor and your symptoms are not relieved or you notice a sudden worsening of your shortness of breath, YOU MAY NEED EMERGENCY TREATMENT.

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.

Drugs that may interact with OXEZE TURBUHALER include:

- beta-blockers (some heart medicines or eye drops).

PROPER USE OF THIS MEDICATION

The dosage of OXEZE TURBUHALER is individual. Follow your doctor’s instructions carefully. They may differ from the information contained in this leaflet.

Asthma:

For the maintenance treatment of asthma, OXEZE TURBUHALER should be taken at the same time with an anti-inflammatory medication, such as a corticosteroid to reduce the inflammation in your lungs due to your asthma. Your anti-inflammatory medication and OXEZE TURBUHALER are designed to work together to best treat your condition. You must continue to regularly take the anti-inflammatory medications your doctor has given you. Even if you feel better, DO NOT STOP or reduce your doses of either the anti-inflammatory medication or OXEZE TURBUHALER without first checking with your doctor.

Usual Adult Dose: 6 mcg or 12 mcg twice a day, taken 12 hours apart. Some adults may need to take 24 mcg, twice a day.

Maximum daily dose: 48 mcg a day.

Usual Child (6-16 years old) Dose: 6 or 12 mcg twice a day, taken 12 hours apart.

Maximum daily dose: 24 mcg a day.

Note to Parents: It is important that you watch your child(ren) to make sure that they take both OXEZE TURBUHALER and an inhaled corticosteroid at the same time. If you cannot ensure that your child(ren) is taking **both** medications at the same time, then talk to your doctor. A combination product may be required.

For the prevention of exercise-induced asthma:

Usual Adult and Child (6 years of age and older) Dose: 6 or 12 mcg before you exercise.

Maximum Adult Dose: 48 mcg in a 24 hour period.

Maximum Child and Adolescent Dose: 24 mcg in a 24 hour period.

Do NOT take more than the dose prescribed by your doctor.

You should see your doctor if:

- your usual dose does not provide relief;
- the effects of one dose last less than 12 hours;
- you use more than 48 mcg of OXEZE TURBUHALER for 3 days in a row.

These may be signs that your asthma is getting worse.

Missed Dose:

If you miss a dose and you remember within 6 hours, you should take it as soon as possible. You should then go back to your regular schedule. However, if it has been more than 6 hours when you remember, do not take the missed dose. Just take the next dose on time.

Never take a double dose of OXEZE TURBUHALER to make up for missed doses. If you are still unsure, check with your doctor or pharmacist to see what you should do.

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.

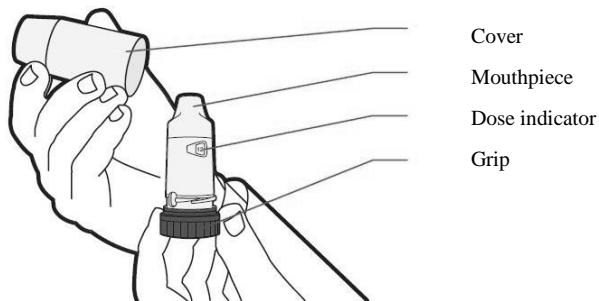
There is no clinical experience on the management of overdose. The most common signs and symptoms of an overdose are:

- trembling;
- headache;
- rapid heartbeat.

HOW TO USE YOUR OXEZE TURBUHALER INHALER

Before you start using OXEZE TURBUHALER for the first time it is important that you read the instructions below and follow them carefully.

TURBUHALER is a multidose inhaler from which very small amounts of powder are administered. When you breathe in through TURBUHALER the powder is delivered to the lungs. It is therefore important that you **inhale as deeply and strongly** as you can through the mouthpiece.



Before you use a **NEW** inhaler for the first time you must prepare the inhaler for use. Follow the steps under “**A. How to prepare a NEW inhaler for use:**”.

For regular use of your inhaler follow the steps under “**B. How to take a dose:**”.

A. How to prepare a NEW inhaler for use:

You only need to prepare your **NEW** inhaler for use **once**. You do not need to repeat these steps even if your inhaler is not used regularly.

STEP 1 Unscrew and lift off the cover (Figure 1). You will hear a rattling sound when you unscrew the cover. This is normal.

Figure 1



STEP 2 Hold the inhaler upright. Do not hold the inhaler by the mouthpiece.

- Turn the **greenish-blue grip** as far as it will go in one direction (clockwise or counter-clockwise, it does not matter which way you turn it first).
- Then turn the greenish-blue grip as far as it will go in the opposite direction (Figure 2).
- At some point when you are turning the grip, **you will hear a “click”**. This is part of the preparation process.

Figure 2



STEP 3 **Repeat STEP 2** one more time. Then follow the steps under “**B. How to take a dose:**”, **starting at STEP 2**.

B. How to take a dose:

To properly take a dose, follow these 4 steps:

STEP 1 Unscrew and lift off the cover (Figure 1). You will hear a rattling sound when you unscrew the cover. This is normal.

Figure 1



STEP 2 Hold the inhaler upright. Do not hold the inhaler by the mouthpiece.

- Turn the **greenish-blue grip** as far as it will go in one direction (clockwise or counter-clockwise, it does not matter which way you turn it first).
- Then turn the greenish-blue grip as far as it will go in the opposite direction (Figure 2).

Figure 2



A dose has now been loaded.

- At some point when you are turning the grip, **you will hear a “click”**. This is part of the loading process.

NOTE: If you accidentally **drop, shake or breathe out** into OXEZE TURBUHALER after the dose has been loaded, you will lose your dose. If this happens, repeat STEP 2 to load a new dose.

STEP 3 **Breathe out**, with your mouth away from the mouthpiece (Figure 3). Then, place the mouthpiece gently between your teeth.

Figure 3



STEP 4 Now close your lips over the mouthpiece. Do not bite or chew the mouthpiece.

- **Inhale as deeply and strongly** as you can (Figure 4).
- You may not feel or taste the medication when inhaling. This is common.
- Before you exhale, remember to remove the inhaler from your mouth.

Figure 4



Repeat STEPS 2-4 if more than one dose has been prescribed. When you have taken the prescribed number of doses, **replace the cover and screw it back on.**

Note: Do not try to take off the mouthpiece or to twist it unnecessarily. The mouthpiece can be rotated but it is fixed to the inhaler and must not be taken off. Do not use the TURBUHALER if it has been damaged.

I cannot remember how many times I turned the greenish-blue grip. What should I do?

The TURBUHALER is designed to load only one dose at a time. If you can't remember how many times you have turned the greenish-blue grip, you can start the process again. Follow the steps below. You will not end up loading two doses.

If you are using a **NEW** inhaler for the first time, start at the beginning of STEP 2 under the section "**A. How to prepare a NEW inhaler for use:**".

For regular use of your inhaler, start at the beginning of STEP 2 under the section "**B. How to take a dose:**".

How do I know my dose has been loaded?

By turning the greenish-blue grip all the way in **BOTH** directions, you will properly load a dose of your medication. At some point when you are turning the grip you will hear a "click". This is part of the loading process. If you are not sure you heard the "click", repeat from the beginning of STEP 2 under the section "**B. How to take a dose:**". This will not result in two doses being loaded. The TURBUHALER is designed to load only one dose at a time.

How do I clean my inhaler?

Clean the outside of the mouthpiece once a week with a dry tissue. Never use water or any other fluid. If fluid enters the inhaler it may not work properly.

How do I know when to start a new inhaler?

OXEZE TURBUHALER has a dose indicator. The dose indicator tells you around how many doses are left in the inhaler. The dose indicator moves slowly each time you load a dose. Every 20th dose is marked with a number and every 10th dose is marked with a dash (Figure 5). For the last 10 doses, the background of the indicator is red. When the "0" on the red background has reached the middle of the window, you should throw out your inhaler and start a new inhaler. The sound you hear if you shake the inhaler is made by a drying agent, not medication. OXEZE TURBUHALER cannot be refilled with the drug and should be thrown away.

Figure 5



SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Usually you do not feel any side effects when you use OXEZE TURBUHALER. However, like any medication,

OXEZE TURBUHALER may cause side effects in some people.

Side effects are:

- headache;
- trembling;
- dizziness;
- nausea;
- muscle cramps;
- skin rash;
- changes in the salt balance in the blood (low potassium levels);
- high blood sugar levels;
- rapid heartbeat;
- sleep disturbances;
- variations in blood pressure;
- hypertension;
- behaviour disturbances;
- agitation;
- restlessness;
- nervousness.

Side effects that do occur are usually mild and disappear by themselves within one or two weeks of treatment, however, be sure to tell your doctor if any of the side effects bother you or if they continue.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist*
		Only if severe	In all cases	
Unknown	Chest pain		X	
	Sudden shortness of breath and wheezing shortly after inhalation of OXEZE			X
	Irregular heartbeat		X	
	Bronchospasm (shortness of breath, chest tightness)			X
	Allergic Reactions Lumpy skin rash or hives anywhere on the body, or itching			X

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist*
	Only if severe	In all cases	
<i>Allergic Reactions</i> Sudden wheeziness and chest pain or tightness; or swelling of eyelids, face or lips			X

***If you think you have these side effects, it is important that you seek medical advice from your doctor immediately.**

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

HOW TO STORE IT

Remember to **keep OXEZE TURBUHALER out of the reach and sight of children.**

Always replace the cover after using OXEZE TURBUHALER. Store the inhaler at room temperature (15-30°C).

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Call toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: 1-800-668-6000.

This leaflet was prepared by:
AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

OXEZE®, TURBUHALER® and the AstraZeneca logo are registered trademarks of AstraZeneca AB, used under license by AstraZeneca Canada Inc.

©AstraZeneca 2000-2018

Last revised: April 23, 2018