

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

# **Pr** OXEZE<sup>®</sup> TURBUHALER<sup>®</sup> formoterol fumarate dihydrate

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 children 6 to 16 years old be strictly supervised to ensure they take both OXEZE TURBUHALER **and** an inhaled corticosteroid. If this cannot be **guaranteed**, speak to the prescribing physician, as 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:

OXEZE TURBUHALER is supplied in two strengths: 6 µg/metered dose (60 doses) and 12 µg/metered dose (60 doses). TURBUHALER is the brand name for a multiple dose, dry powder inhaler. When you breathe in through the mouthpiece, your breath provides the necessary force to deliver the drug to your lungs.

#### 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 physician when your asthma is assessed as adequately under control (step-down therapy).

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

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)
- about all medicines you take, including those you have bought without a prescription
- 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**

Drugs that may interact with OXEZE TURBUHALER include: certain types of medicines - for example, beta-blockers (some heart medicines or eye drops) which may reduce or block the effect of OXEZE TURBUHALER when taken at the same time.

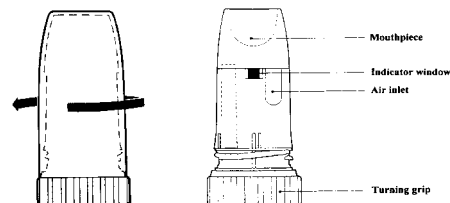
### **PROPER USE OF THIS MEDICATION**

**Before using OXEZE TURBUHALER, read this leaflet carefully.** It contains general points about OXEZE TURBUHALER and should add to more specific advice from your doctor or pharmacist.

Please keep this leaflet to refer to until you have used up all medication in OXEZE TURBUHALER.

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

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 forcefully and deeply through the mouthpiece.



OXEZE TURBUHALER is **very** easy to use.

**Note:** You may not taste or feel any medication when inhaling from OXEZE TURBUHALER. This is common.

**If you follow the instructions below, you will receive the medication.**

#### **Using the inhaler:**

To administer a dose, simply follow the instructions below. Unscrew and lift off the cover.

Fig. 1

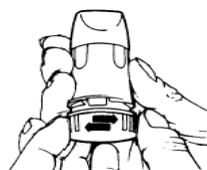


Fig. 2



**TURN:** Hold the inhaler upright with the grip downwards (Fig. 1). To load the inhaler with a dose **turn the greenish-blue grip as far as it will go in one direction and then back to the original position.**

**CLICK:** The “click” you heard means the inhaler is ready to use. **Breathe out.** Do **not** breathe out through the mouthpiece. **INHALE:** Place the mouthpiece gently between your teeth, close your lips and breathe in **forcefully and deeply** through your mouth (Fig. 2). Do not chew or bite on the mouthpiece.

**Note:** Do not use TURBUHALER if it has been damaged or if the mouthpiece has become detached. **Remove the inhaler from your mouth, before breathing out.**

If more than one dose has been prescribed, repeat the above steps. Replace the cover.

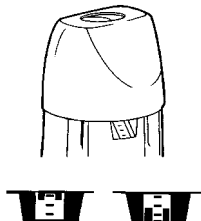
If you accidentally drop, shake or breathe out into OXEZE TURBUHALER after it is loaded, you will lose your dose. If this happens, you should load a new dose and inhale it.

**Note:** **Never breathe out through the mouthpiece. Always replace the cover properly after use.**

As the amount of powder dispensed is very small, you may not be able to taste it after inhalation. However, you can still be confident that the dose has been inhaled if you have followed the instructions.

**Cleaning:** 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 you know when OXEZE TURBUHALER is empty?**



Approx. 20 doses left **EMPTY**

OXEZE TURBUHALER has a dose indicator. A new TURBUHALER provides 60 doses for inhalation. When a red mark first appears in the little window underneath the mouthpiece, there are approximately 20 doses left. Now is the time to obtain your next inhaler.

When the red mark reaches the bottom of the window, you should discard your inhaler. The sound you hear when you shake the inhaler is produced by a drying agent, not medication. OXEZE TURBUHALER cannot be re-filled with drug and should be discarded.

**How do you identify your different asthma medications?**

You may be prescribed the following AstraZeneca medications to help control your asthma. It is important that you understand how to tell them apart and when to use each medication. Before use, carefully read the label on each TURBUHALER device.

Medication	Strength	Identification
OXEZE TURBUHALER (formoterol)	6 µg/dose	Turning grip is light greenish-blue.  A braille code is embossed on the turning grip.
OXEZE TURBUHALER (formoterol)	12 µg/dose	Turning grip is dark greenish-blue.  A braille code is embossed on the turning grip.
PULMICORT® TURBUHALER (budesonide)	100 µg/dose	Turning grip is light brown.  Budesonide 100 is embossed on the turning grip.

Medication	Strength	Identification
PULMICORT TURBUHALER (budesonide)	200 µg/dose	Turning grip is brown.  Budesonide 200 is embossed on the turning grip.
PULMICORT TURBUHALER (budesonide)	400 µg/dose	Turning grip is dark brown.  Budesonide 400 is embossed on the turning grip.
BRICANYL® TURBUHALER (terbutaline)	0.5 mg/dose	Turning grip is blue.  Terbutaline sulfate 0.5 mg/dose is embossed on the turning grip.

Specific information on product identification is provided on the drug product label. Ask your doctor or pharmacist for clarification if you are having difficulty understanding when or how often your medications should be taken.

**Usual Dose:**

**Asthma:**

**Adults**

The usual dose is 6 or 12 µg, twice daily, at 12 hour intervals. Some adults may need 24 µg, twice daily. In adults, the maximum recommended daily dose is 48 µg.

**Children (6-16 years)**

The usual dose is 6 or 12 µg, twice daily, at 12 hour intervals. In children, the maximum recommended daily dose is 24 µg.

**Note to Parents:** It is important that children 6 to 16 years old be strictly supervised to ensure they take both OXEZE TURBUHALER **and** an inhaled corticosteroid. If this cannot be **guaranteed**, speak to the prescribing physician, as a combination product may be required.

**For the prevention of exercise-induced asthma:**

**Adults and Children 6 years of age and older**

6 or 12 µg before exercise.

The maximum dose during a 24 hour period 48 µg in adults and 24 µg in adolescents and children.

OXEZE TURBUHALER is not recommended for children younger than 6 years.

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 µg of OXEZE TURBUHALER on 3 days in a row.

These may be signs that your asthma is getting worse.

**Do NOT exceed the dose prescribed by your doctor.**

**For maintenance treatment of asthma, OXEZE TURBUHALER should be taken together with an anti-inflammatory medication, such as a corticosteroid, to reduce inflammation of the lungs due to asthma.**

You must continue to regularly take the anti-inflammatory medications your doctor has prescribed. Your anti-inflammatory medications and OXEZE TURBUHALER are designed to act together to best treat your condition. Even though you feel better, **DO NOT STOP** or reduce your doses of anti-inflammatory medications or OXEZE TURBUHALER without first consulting your doctor.

**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 that may occur after overdosage are trembling, headache and rapid heartbeat.

**Missed Dose:**

If you miss a dose of your twice daily maintenance treatment of OXEZE TURBUHALER and remember within 6 hours, you should take your usual dose as soon as possible. Then go back to your regular schedule. If it is 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.

**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.

The most common side effects are trembling, rapid heartbeat, and headache. Rare or uncommon side effects are muscle cramps, skin rash, agitation, restlessness and sleep disturbances.

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. Also contact your doctor if any other unusual effects bother you while you are using OXEZE TURBUHALER.

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	
Very Rare	Chest pain		X	
	Sudden shortness of breath and wheezing shortly after inhalation of OXEZE			X
Rare	Irregular heartbeat		X	
	Bronchospasm (shortness of breath, chest tightness)			X
	<i>Allergic Reactions</i> Lumpy skin rash or hives anywhere on the body			X
	<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 of children.**

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

## **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](http://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 0701C  
Ottawa, ON K1A 0K9****

**Postage paid labels, Canada Vigilance Reporting Forms and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://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 INFORMATION FOR THE CONSUMER 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](http://www.astrazeneca.ca), or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1 (800) 668-6000, Renseignements – 1 (800) 461-3787.

**Important Note:** This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using OXEZE TURBUHALER.

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