

PART III: CONSUMER INFORMATION

PrZENHALE™

mometasone furoate / formoterol fumarate dihydrate inhalation aerosol

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

Your doctor has prescribed ZENHALE™ to help control asthma.

ZENHALE™ is used twice a day to help people 12 years of age or older who need treatment for asthma and the doctor recommends a combination product. ZENHALE™ is not a rescue medication. Your doctor should prescribe a rescue medication for you. Use the rescue medication if you have sudden asthma symptoms.

ZENHALE™ is for patients with asthma that:

- was not well controlled with other asthma controlling medications or
- is severe enough that the doctor recommends starting asthma treatment with two asthma medications

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 it does:**

ZENHALE™ contains two medicines, mometasone furoate and formoterol fumarate dihydrate:

- Mometasone furoate is a corticosteroid. Corticosteroids are used to prevent asthma attacks because they have an anti-inflammatory effect (reduce swelling and irritation in the walls of the small air passages of the lungs, easing breathing problems).
- Formoterol fumarate dihydrate is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. It makes breathing easier by relaxing muscle spasms in the air passages of the lungs. The effects last for 12 hours.

**When it should not be used:**

**Do not take ZENHALE™**

- if you are allergic (hypersensitive) to mometasone furoate, formoterol fumarate dihydrate or any of the ingredients contained in the product.
- if you are under 12 years of age.

**What the medicinal ingredients are:**

mometasone furoate and formoterol fumarate dihydrate.

**What the nonmedicinal ingredients are:**

ZENHALE™ is suspended in a propellant (HFA-227), with ethanol and oleic acid.

**What dosage forms it comes in:**

ZENHALE™ is supplied to you in an inhaler containing 50, 100 or 200 micrograms of mometasone furoate and 5 micrograms of formoterol fumarate per actuation (puff).

**WARNINGS AND PRECAUTIONS**

**Serious Warnings for Asthma Patients**

Formoterol, one of the medicines in ZENHALE™, may increase the risk of asthma-related death. It may increase the risk of asthma-related hospitalization in paediatrics and adolescent patients. Therefore:

- Your doctor will assess your asthma control at regular intervals. ZENHALE™ should only be used when your doctor decides that other asthma medications (e.g. inhaled glucocorticosteroids along with an as needed relief medication) are not helping you enough, or that you need two maintenance medications to control your asthma.
- ZENHALE™ should not be the first medication you use, unless advised by your doctor.

Once asthma control has been achieved and maintained, your doctor will assess you at regular intervals. ZENHALE™ should only be used when an inhaled corticosteroid does not adequately control your asthma symptoms.

BEFORE you use ZENHALE™ talk to your doctor or pharmacist if:

- you are diabetic
- you have high blood pressure or you have ever had a heart problem
- you have liver disease or cirrhosis
- you have problems with your thyroid or adrenal glands
- you have low levels of potassium in your blood
- you have or have ever had tuberculosis
- you have herpes simplex (virus) infection of the eye or any other type of untreated infection

If you are pregnant, planning to get pregnant or are breastfeeding talk to your doctor before using ZENHALE™.

### **Important things to remember when using ZENHALE™**

- If symptoms get worse (increased use of a 'reliever' medication peak flow measurement falls, your symptoms are waking you up at night) or do not get better after using ZENHALE™, you should contact your doctor as soon as possible.
- ZENHALE™ should not be used to treat sudden asthma symptoms.
- Do not stop taking ZENHALE™ on your own, even if you feel better. Your doctor can direct you on how to discontinue ZENHALE™ slowly to avoid asthma flare-ups.
- If you are transferring to ZENHALE™ from steroid tablets or syrup and your doctor is slowly decreasing the dose, you may notice that you develop symptoms of allergies such as itchy, watery eyes or rash, which had been controlled by your steroid. Your doctor will tell you how to control these symptoms. During this time, if you begin to notice joint or muscle pain, feelings of depression, tiredness or lethargy, you should tell your doctor.
- You may need to also take steroid tablets or syrup during a severe asthma attack, during other illnesses or during times of stress. Your doctor may give you some steroid tablets or a syrup to carry with you as well as a steroid warning card, which will give you advice on when and how to use them.
- Adolescents 12 years and older treated with ZENHALE™ may grow more slowly than others.
- While using inhaled corticosteroids, patients should avoid coming into contact with anyone who has measles or chicken pox. If you or your child are exposed, tell your doctor right away.
- While using inhaled corticosteroids, patients should be monitored for signs of cataracts, glaucoma (see your eye doctor regularly) or of osteoporosis (decreased bone density).

## **INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist if you are taking or have recently taken any other medications.

### **Drugs that may interact with ZENHALE™ include:**

- Beta-blocker medicines (such as atenolol or propranolol used for high blood pressure) including eye drops (such as timolol eyedrops for glaucoma)
- Ketoconazole (an antifungal medicine)
- Corticosteroids (by mouth or by injection)
- Diuretics (water pills)
- Xanthine medicines (such as theophylline and aminophylline) used to treat asthma
- Medicines for a fast or uneven heartbeat (such as quinidine)
- Tricyclic anti-depressants
- Monoamine oxidase inhibitors (MAOIs)
- Terfenadine or astemizole (an antihistamine used to treat allergies)
- Other medicines containing a long-acting beta<sub>2</sub>-agonist (i.e. formoterol, salmeterol)
- disopyramide, procainamide or phenothiazines

Make sure that your doctor or pharmacist knows what other medications you are taking, including those you can buy without a prescription and as natural health products.

## **PROPER USE OF THIS MEDICATION**

Always take ZENHALE™ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

As prescribed by your doctor, you should always carry a 'reliever' medication such as salbutamol with you. Use your 'reliever' medication if your asthma symptoms occur between doses. If your 'reliever' medication becomes less effective, seek medical attention right away.

### **Usual dose:**

Your doctor will decide the best dose for your individual case. The usual dose is 2 puffs in the morning and 2 puffs in the evening. It is important that you use ZENHALE™ every day, even if you have no asthma symptoms at the time.

Do not exceed the dosage of ZENHALE™ recommended to you by your doctor.

## Instructions for use

### The parts of your ZENHALE™ inhaler

There are two main parts (see figure 1):

- The metal canister that holds the medicine.
- The blue plastic actuator that sprays the medicine from the canister. The mouthpiece of the actuator is covered by a cap.

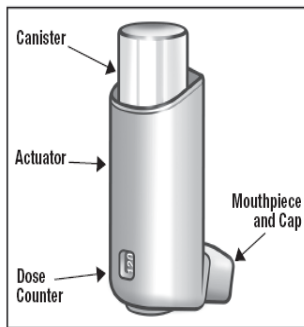


Figure 1

The inhaler contains 120 actuations (puffs).

The inhaler comes with a dose counter located on the plastic actuator. The dose counter display will show the number of actuations (puffs) of medication remaining. The dose counter will initially display “124” actuations remaining. Each time you press the canister, a puff of medicine is released and the counter will count down by one. The counter will stop counting at 0.

It is recommended not to remove the canister from the actuator because reinsertion may cause the counter to count down by one and/or discharge a puff.

Use the ZENHALE™ canister only with the actuator supplied with the product. Parts of the ZENHALE™ inhaler should not be used with parts from any other inhalation drug product.

### Before using your ZENHALE™ inhaler

Remove the cap from the mouthpiece of the actuator (see figure 2). Check the mouthpiece for foreign objects and make sure the canister is fully inserted into the actuator.

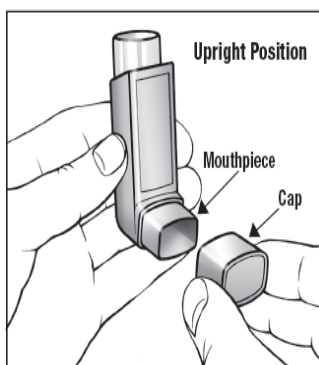


Figure 2

It is necessary to prime the inhaler into the air the first time it is used. Prime the inhaler by releasing four actuations (puffs) into the air, away from your face. Shake the inhaler well before each of the priming actuations. After priming four times, the dose counter should read “120”. It is also necessary to prime the inhaler when it has not been used for more than five days using four actuations (puffs).

### How to use your ZENHALE™ inhaler properly

Be in an upright position when using ZENHALE™.

#### Avoid spraying in your eyes

1. Remove the cap from the mouthpiece of the actuator.
2. Hold the aerosol can upright between your thumb and forefinger **and shake the inhaler**.
3. Breathe out fully through the mouth as far as is comfortable, expelling as much air from your lungs as possible. Hold the inhaler in the upright position and place the mouthpiece into your mouth. Close your lips around the mouthpiece (see figure 3).

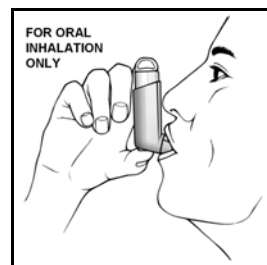


Figure 3

4. While breathing in deeply and slowly through your mouth, press down firmly and fully on the canister top until it stops moving in the actuator. Take your finger off the canister.
5. When you have finished breathing in, hold your breath for up to 10 seconds, or for as long as is comfortable. Then remove the inhaler from your mouth and breathe out through your nose while keeping your lips closed.
6. For administration of the second actuation (puff), wait about **30 seconds, shake the inhaler well again and repeat** steps 3 through 5.
7. Firmly replace the cap immediately after use. Do not use excessive force.
8. After completing both inhalations, rinse out your mouth thoroughly with water. Do not swallow the water after rinsing.

### When to replace your ZENHALE™ inhaler

When the counter reads 20, you should refill your prescription or ask your doctor if you need a new prescription for ZENHALE™.

Discard ZENHALE™ after the counter reaches 0, indicating that you have used the number of actuations on the product label and box. Your inhaler may not feel empty and it may continue to operate, but you will not get the right amount of medicine if you keep using it.

Never try to change the numbers on the counter or remove the counter from the actuator.

**How to clean your ZENHALE™ inhaler**

The mouthpiece should be cleaned using a dry wipe after every 7 days of use.

Routine cleaning instructions:

- Remove the cap off the mouthpiece. Wipe the inside and outside surfaces of the actuator mouthpiece with a clean, dry lint-free tissue or cloth. Put the cap back on the mouthpiece after cleaning.
- Do not attempt to unblock the actuator with a sharp object, such as a pin.
- **Do not wash or put any parts of your inhaler in water.**

**Use with a spacer**

If necessary, your doctor will prescribe the use of a spacer to help you properly take this medication. Instructions provided with the spacer device should be consulted prior to use.

**Overdose:**

If you use more ZENHALE™ than you should, contact your doctor or pharmacist.

The most common symptoms that may occur if you use more ZENHALE™ than you should are nausea, vomiting, headache, trembling, drowsiness, low potassium levels, high sugar levels, or a rapid or irregular heart beat.

If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of ZENHALE™ may reduce the amount of steroid hormones produced by the adrenal gland.

**In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms.**

**Missed Dose:**

If you miss a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose.

**Do not suddenly stop using this medicine even if your asthma seems to be better. Speak with your doctor first.**

Your symptoms may come back if you stop using this medicine before your doctor has told you to do so. If you think that your asthma is not getting any better or seems to be getting worse, after you have started using ZENHALE™ go back and see your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, ZENHALE™ can cause side effects, although not everybody gets them.

Side effects may include nausea, headache, hoarseness, tremor, shakiness, nervousness, dizziness, disturbed sleep, muscle cramps, sore throat, rounded face, loss of bone density and dry mouth.

**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 seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Thrush: a fungal infection in the mouth. Thrush is less likely to occur if you rinse your mouth with water and spit after using ZENHALE™.		√	
Un-common	Fast or uneven heartbeat		√	
	High blood pressure		√	
Rare	Allergic reaction: rash, itching, hives, redness or swelling of the eyes, lips and throat, trouble breathing or joint pain			√
	Increased pressure in the eye (glaucoma) or cataracts (clouding of the lens in the eye), blurry vision, eye pain		√	
	Sudden coughing, wheezing and difficulty breathing (bronchospasm) when you inhale ZENHALE™			√ If you notice this, use your "reliever" inhaler and contact your doctor straightaway.

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

## HOW TO STORE IT

**Keep your medicine in a safe place out of the reach and sight of children. Your medicine may harm them.**

- Store ZENHALE™ between 15°C to 30°C. If the inhaler is exposed to low temperatures, warm it to room temperature (by warming in the hand) before use.
- Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C.

**WARNING:** Do not use ZENHALE™ after the expiry date which is stated on the carton and the can. The expiry date refers to the last day of that month.

Do not use ZENHALE™ if you notice that the pack is damaged or shows signs of tampering.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 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:
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
Ottawa, ON 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](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

You may need to read this package insert again. **Please do not throw it away** until you have finished your medicine.

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor at:

### **Merck Canada Inc.**

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1-800-463-5442

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