

PART III: CONSUMER INFORMATION

ZENHALE®

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.
- to treat a sudden attack of breathlessness. You may need another medicine (i.e. fast acting 'reliever' medication) in a different inhaler. You should always carry the 'reliever' medication that your doctor has prescribed, just in case you experience a sudden attack of asthma.
- if you have an untreated infection (fungal, bacterial, viral or parasitic) or tuberculosis infection of the respiratory tract.
- if you have herpes simplex infection in the eye.
- if you are under 12 years of age.
- if you have a heart problem called tachyarrhythmia (fast and/or irregular heart beat).

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 mcg of mometasone furoate and 5 mcg of formoterol fumarate per actuation (puff). The inhaler contains 60 or 120 actuations (puffs).

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
- have high blood pressure
- have ever had a heart problem, such as rapid or irregular heart beat or abnormal electrical signal called “prolongation of the QT interval”
- have liver disease or cirrhosis
- have problems with your thyroid or adrenal glands
- have low levels of potassium in your blood
- have or have ever had tuberculosis
- have a fungal infection (thrush) in your mouth or throat
- have eye disorders such as glaucoma or cataracts
- have hypoprothrombinemia (a blood clotting problem) and are taking acetylsalicylic acid (aspirin)
- have an aneurysm (area where an artery is swollen like a sack because the wall of the artery is weak)
- have pheochromocytoma (a tumor of the adrenal gland that can affect blood pressure)
- are pregnant, planning to get pregnant or are breastfeeding.

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.
- You 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).
- When using drugs like ZENHALE[®] for long term treatment, you may be at risk of:
 - Breaking a bone (bone fractures);
 - Osteoporosis (increased risk of bone fractures).
 - Take extra care to avoid any injury, especially falls.
- Drugs like ZENHALE[®] can cause eye disorders:
 - Cataracts: clouding of the lens in the eye, blurry vision, eye pain;
 - Glaucoma: An increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss;
 - You should therefore have regular eye exams
- If you notice the following symptoms: a flu-like illness, rash, pins and needles or numbness of arms or legs, severe sinusitis and worsening lung or breathing problems, this can be a sign of Churg-Strauss syndrome. This can happen in people with asthma who are using inhaled corticosteroids. Tell your healthcare provider right away if these symptoms occur.

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, itraconazole (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 beta₂-agonist (i.e. formoterol, salmeterol)
- Disopyramide, procainamide or phenothiazines
- Ritonavir, atazanavir, indinavir, nelfinavir, saquinavir (an anti-HIV medicine)
- Macrolide antibiotics (e.g. erythromycin, azithromycin, clarithromycin)
- Cobicistat-containing products

- Inhaled anaesthetics such as halogenated hydrocarbons (e.g. halothane), used during surgery. Inform your doctor that you use ZENHALE[®] if you are to have surgery under anaesthesia.
- Acetylsalicylic acid (aspirin) if you have hypoprothrombinemia.

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 three main parts (see figure 1):

- The metal canister that holds the medicine.
- The blue plastic actuator that sprays the medicine from the canister.
- The green cap that covers the mouthpiece of the actuator.

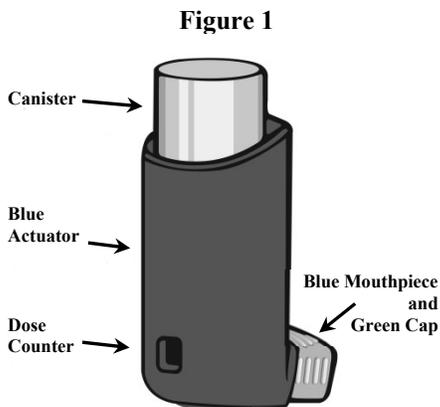


Figure 1

The inhaler contains 60 or 120 actuations (puffs).

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

You must prime the inhaler into the air before the first time it is used.

- To prime the inhaler, remove the cap from the mouthpiece, hold it in the upright position and release 4 actuations (puffs) into the air, away from your face.
- Shake the inhaler well before each of the priming actuations. After priming 4 times, the dose counter should read either "60" or "120".
- Prime the inhaler again when it has not been used for more than 5 days.

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 (Figure 2).

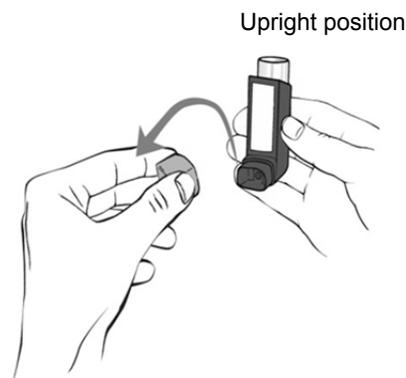


Figure 2

2. Check the mouthpiece for foreign objects and make sure the canister is fully inserted into the actuator.
3. Hold the aerosol can upright between your thumb and forefinger **and shake the inhaler**.
4. Breathe out fully through your 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).

FOR ORAL INHALATION ONLY



Figure 3

5. 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.
6. 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.
7. For administration of the second puff, wait about **30 seconds, shake the inhaler well again and repeat** steps 4 through 6.
8. Firmly replace the cap immediately after use (see figure 4). Do not use excessive force.



Figure 4

9. After completing both inhalations, rinse your mouth thoroughly with water. Do not swallow the water after rinsing.

The Dose Counter

The inhaler comes with a dose counter located on the plastic actuator (See figure 5).



Figure 5

- The dose counter identifies the number of actuations (puffs) left in your inhaler. The dose counter will initially display “64” or “124” actuations (puffs) remaining.
- The counter will count down by one each time you release a puff of medicine (either when preparing your ZENHALE[®] inhaler for use or when taking the medicine).
- The counter will stop counting at 0.

YOU SHOULD NOT REMOVE THE CANISTER FROM THE ACTUATOR because:

- You may not receive the correct amount of medication.
- The dose counter may not function properly.
- Reinsertion may cause the counter to count down by 1 and may discharge a puff.

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.

Warning: Do not use the inhaler after the expiration date.

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. **Do not wash or put any parts of your inhaler in water.** Put the cap back on the mouthpiece after cleaning.
- Do not remove the canister from the actuator.
- Do not attempt to unblock the actuator with a sharp object, such as a pin.

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, high blood pressure 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
- fainting
- 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 (yeast infection in the mouth): White patches in the mouth and on the tongue, sore throat. Thrush is less likely to occur if you rinse your mouth with water and spit after using ZENHALE®.		√	
Uncommon	Fast or uneven heartbeat		√	
	High blood pressure		√	

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	
Rare	Allergic reaction: Low blood pressure, rash, itching, hives, redness or swelling of the eyes, lips and throat, trouble breathing or joint pain			√
	Glaucoma: Increased pressure in the eye			
	Cataracts: (clouding of the lens in the eye), blurry vision, eye pain		√	
	Central Serous Chorioretinopathy: Distorted vision/blurred vision		√	
	Bronchospasm: Sudden coughing, wheezing and difficulty breathing when you inhale ZENHALE®			√ If you notice this, use your “reliever” inhaler and contact your doctor straightaway.
Unknown	Decreased levels of potassium in the blood: irregular heartbeat, muscle weakness and generally feeling unwell			√
	Increased blood sugar: frequent urination, thirst and hunger			√
	Chest Pain			√
	Worsening of asthma: coughing, shortness of breath, wheezing and difficulty breathing			√
	Churg-Strauss Syndrome: A flu-like illness, rash, pins and needles or numbness of arms and legs, severe sinusitis and worsening lung or breathing problems.		√	

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	
	Decreased adrenal function: Tiredness, weakness, nausea and vomiting, low blood pressure.		√	

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.
- The 120-actuation inhaler can be stored in any position. For the 60-actuation inhalers, after priming, store the inhaler with the mouthpiece down or sideways.
- 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.

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 SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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

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

If you want more information about ZENHALE®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the [Health Canada website](#) (www.hc-sc.gc.ca) or [www.merck.ca](#) or by calling 1-800-567-2594

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