

ZENHALE®

Mometasone Furoate/Formoterol Fumarate Dihydrate (50/5mcg, 100/5mcg, 200/5mcg)

What is in this leaflet

1. What ZENHALE is used for
2. How ZENHALE works
3. Before you use ZENHALE
4. How to use ZENHALE
5. While you are using ZENHALE
6. Side effects
7. Storage and Disposal of ZENHALE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What ZENHALE 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.

How ZENHALE works

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.

Before you use ZENHALE

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.

- When you must not use it

Do not take ZENHALE

- If you are allergic (hypersensitive) to mometasone furoate, formoterol fumarate, or any of the other ingredients of ZENHALE.
- To treat a sudden attack of breathlessness, you may need another medicine (i.e. fast acting rescue medication) in a different inhaler. You should always carry the rescue 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.

- Before you start to use ZENHALE

Tell your doctor or pharmacist if you:

- are diabetic

- have high blood pressure or you have ever had a heart problem
- have liver disease or cirrhosis (a type of chronic liver disease)
- have problems with your thyroid or adrenal glands
- have low levels of potassium in your blood
- have or have ever had tuberculosis (TB)
- have hypoprothrombinemia (a blood clotting problem that occurs when there is a reduced amount of a substance (prothrombin) that is needed for blood to clot) 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 tumour of the adrenal gland that can affect blood pressure)

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

- Taking other medicines

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

Drugs that may interact with ZENHALE include:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).
- Ketoconazole, itraconazole (antifungal medications).
- Corticosteroids (by mouth or by injection).
- Diuretics (water pills).
- Xanthine medicines (such as theophylline or aminophylline) to treat asthma.
- Medicines for a fast or uneven heart beat (such as quinidine).
- Tricyclic anti-depressants.
- Mono-amine oxidase inhibitors (MAOIs).
- Terfenadine or astemizole (an antihistamine used to treat allergies).
- Other medicines containing a long-acting beta₂-agonists (such as formoterol or salmeterol).
- Disopyramide, procainamide or phenothiazines.

- Ritonavir, atazanavir, indinavir, nelfinavir, saquinavir (an anti-HIV medicine).
- Macrolide antibiotics (e.g. erythromycin, azithromycin, clarithromycin).
- 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.

How to use ZENHALE

- How much to use

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

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

-When to use it

It is important that you use ZENHALE every day, even if you have no asthma symptoms at the time.

ZENHALE is not a rescue medication.

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

- How long to use it

Do not suddenly stop using this medicine even if your asthma seems to be better. Talk to 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 contact your doctor.

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

Instructions for use

The parts of your ZENHALE inhaler

There are 3 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.

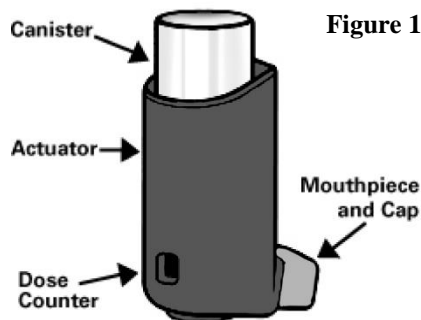


Figure 1

The inhaler contains 120 actuations (puffs).

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

Before using your ZENHALE inhaler

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 (puffs). 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 (see Figure 2).

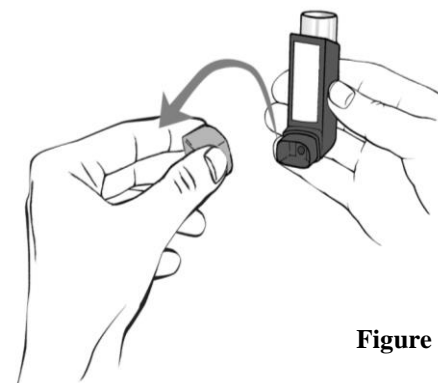


Figure 2

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 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).

FOR ORAL INHALATION ONLY



Figure 3

5. While breathing in deeply and slowly through the 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 actuation (puff), wait at least **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.

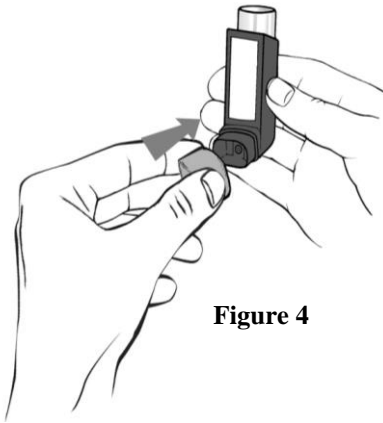


Figure 4

9. After completing both inhalations, rinse out 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).

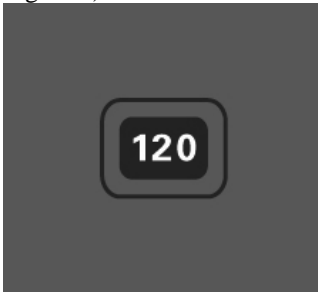


Figure 5

- The dose counter identifies the number of actuations (puffs) left in your inhaler. The dose counter will initially display “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).
- **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 medicine 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. 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.

- If you forget to use ZENHALE

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.

- If you use too much (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 heartbeat.

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.

While you are using ZENHALE

- Things you must do

- If symptoms get worse (increased use of a rescue medication, peak flow measurement falls, your symptoms are waking you up at night) or do not get better after using ZENHALE, contact your doctor as soon as possible.

- Things you must not do

- 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.

- Things to be careful of

- 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, 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 medicines like ZENHALE may grow more slowly than others. Your doctor may check you height from time to time.

- While using inhaled corticosteroids, patients should avoid coming into contact with anyone who has measles or chicken pox. If you or your child is 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).
- 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.

Side effects

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.

Possible serious side effects are:

- **Thrush (a fungal infection in your mouth). Thrush is less likely to occur if you rinse your mouth with water and spit after using ZENHALE.**
- **Fast or uneven heartbeat**
- **High blood pressure**
- **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 rescue inhaler and contact your doctor straightaway**
- **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**

This is not a complete list of side effects. Contact your doctor or pharmacist if you experience any side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI).

Storage and Disposal of ZENHALE

- Storage

- Keep your medicine in a safe place out of the reach and sight of children. Your medicine may harm them.
- Do not use ZENHALE after the expiry date printed on the carton or on the label of your ZENHALE. The expiry date refers to the last day of that month.
- Store at or below 30°C. Do not freeze. For best results, the inhaler should be warmed to room temperature before use (e.g. by warming in the hands) if it is exposed to low temperatures.
- For best results, the canister should be at room temperature before use. Shake well before using. Keep out of reach of children. Avoid spraying in eyes.
- 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.

- Disposal

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

Product Description

- What it looks like

ZENHALE is supplied to you in a metered dose inhaler which delivers your medicine in a pressurised suspension for you to inhale.

The inhaler has a blue actuator with an integrated dose counter displaying the number of puffs remaining and a mouthpiece. The pressurised canister contains a white to off white suspension for inhalation.

The device is packed in cartons containing one ZENHALE.

- Ingredients

- The active substances are mometasone furoate and formoterol fumarate dihydrate. Each puff contains 50, 100 or 200 micrograms mometasone furoate and 5 micrograms formoterol fumarate dihydrate.
- The other ingredients are hydrofluoroalkane-227 (HFA-227), ethanol anhydrous and oleic acid.

- MAL number:

- 50/5mcg: MAL12105066ACRZ
- 100/5mcg: MAL12105065ACRZ
- 200/5mcg: MAL12105067ACRZ

Manufacturer

3M Health Care Ltd
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Product Registration Holder

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Selangor, Malaysia

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