

Patient Information
ASMANEX[®] HFA (AZ-ma-neks) 50 mcg
ASMANEX[®] HFA 100 mcg
ASMANEX[®] HFA 200 mcg
(mometasone furoate)
Inhalation Aerosol

What is ASMANEX HFA?

ASMANEX HFA is an inhaled corticosteroid (ICS) prescription medicine used as maintenance treatment for the prevention and control of asthma symptoms in people 5 years of age and older.

- ASMANEX HFA is not used to treat sudden severe symptoms of asthma.
- ASMANEX HFA should not be used as a rescue inhaler.
- It is not known if ASMANEX HFA is safe and effective in children less than 5 years of age.

Who should not use ASMANEX HFA?

Do not use ASMANEX HFA:

- to treat sudden severe symptoms of asthma.
- if you are allergic to mometasone furoate or any of the ingredients in ASMANEX HFA. See the end of this Patient Information leaflet for a complete list of ingredients in ASMANEX HFA.

What should I tell my doctor before and during treatment with ASMANEX HFA?

Before you use ASMANEX HFA, tell your healthcare provider if you:

- have liver problems.
- have osteoporosis.
- have an immune system problem.
- have eye problems such as increased pressure in the eye, glaucoma, cataracts, blurred vision, or other changes in your vision.
- are allergic to any medicines.
- are exposed to chickenpox or measles.
- have or had tuberculosis (TB).
- have any other medical problems.
- are pregnant or planning to become pregnant. It is not known if ASMANEX HFA may harm your unborn baby.
- are breastfeeding. It is not known if ASMANEX HFA passes into your breast milk and if it can harm your baby. You and your healthcare provider should decide if you will either take ASMANEX HFA or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ASMANEX HFA may affect the way other medicines work, and other medicines may affect how ASMANEX HFA works.

Especially, tell your healthcare provider if you take antifungal medicines, antibiotic medicines, or anti-HIV medicines such as:

- | | | | | |
|----------------------------------|------------------|--------------|-----------------|----------------|
| • ritonavir | • ketoconazole | • nefazodone | • nelfinavir | • indinavir |
| • atazanavir | • clarithromycin | • saquinavir | • telithromycin | • itraconazole |
| • cobicistat-containing products | | | | |

Ask your healthcare provider if you are not sure if any of your medicines are the kinds listed above.

For some medicines (including medicines for HIV such as ritonavir, cobicistat-containing products, and certain antifungals and antibiotics) your doctor may wish to monitor you carefully.

Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist each time you get a new medicine.

How should I use ASMANEX HFA?

Read the step-by-step instructions for using ASMANEX HFA in the Instructions for Use.

- Use ASMANEX HFA exactly as prescribed. **Do not** use ASMANEX HFA more often than prescribed.
- You must use ASMANEX HFA regularly. It may take 1 week or longer after you start using ASMANEX HFA for your asthma symptoms to get better. Do not stop using ASMANEX HFA even if you are feeling better, unless your healthcare provider tells you to.
- **Do not** change or stop using ASMANEX HFA or other asthma medicines used to control or treat your breathing problems unless told to do so by your healthcare provider. Your healthcare provider will change your medicines as needed.
- ASMANEX HFA comes in 3 strengths. Your healthcare provider has prescribed the strength that is best for you. Pay attention to the differences between ASMANEX HFA and your other inhaled medicines, including their prescribed use and the way they look.
- For children aged 5 to less than 12 years, use ASMANEX HFA 50 mcg.
- For adults and adolescents 12 years of age and older, use ASMANEX HFA 100 mcg or 200 mcg.

- Take ASMANEX HFA every day, with 2 puffs in the morning and 2 puffs in the evening.
- If you miss a dose of ASMANEX HFA, skip your missed dose and take your next dose at your regular time. Do not take ASMANEX HFA more often or use more puffs than you have been prescribed.
- If you take more ASMANEX HFA than your healthcare provider has prescribed, call your healthcare provider right away.
- ASMANEX HFA does not relieve sudden asthma symptoms. Always have a rescue inhaler with you to treat sudden symptoms. Use your rescue inhaler if you have breathing problems between doses of ASMANEX HFA. If you do not have a rescue inhaler, call your healthcare provider to have a rescue inhaler prescribed for you.
- Do not use the ASMANEX HFA canister or actuator with any other medicines. Do not use any other medicine canister or actuator with ASMANEX HFA.
- Rinse your mouth with water after each dose (2 puffs) of ASMANEX HFA. Spit out the water. Do not swallow it. This will help to lessen the chance of getting a yeast infection (thrush) in your mouth and throat.
- Do not spray ASMANEX HFA in your eyes. If you accidentally get ASMANEX HFA in your eyes, rinse your eyes with water and if redness or irritation continues, call your healthcare provider.
- **Call your healthcare provider or get medical care right away if:**
 - your breathing problems worsen with ASMANEX HFA
 - you need to use your rescue inhaler more often than usual
 - your rescue inhaler does not work as well for you at relieving symptoms
 - you need to use 4 or more inhalations of your rescue inhaler for 2 or more days in a row
 - you use 1 whole canister of your rescue inhaler within 8 weeks
 - your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.
 - you have asthma and your symptoms do not improve after using ASMANEX HFA regularly for 1 to 2 weeks

What are the possible side effects of ASMANEX HFA?

ASMANEX HFA can cause serious side effects, including

- **Thrush in your mouth and throat.** You may develop thrush, a yeast infection (*Candida albicans*), in your mouth or throat. After each dose (2 puffs) of ASMANEX HFA, rinse your mouth with water. Spit out the water. Do not swallow it. This will help to prevent thrush in your mouth or throat.
- **Immune system effects and a higher chance for infections.**
Tell your healthcare provider about any signs of infection such as:
 - fever ○ feeling tired ○ body aches ○ vomiting ○ pain ○ nausea ○ chills
- **Adrenal insufficiency that can lead to death** can happen when you stop taking oral corticosteroid medicines and start using inhaled corticosteroid medicines. Adrenal insufficiency can also happen in people who take higher doses of ASMANEX HFA than recommended over a long period of time. When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse. Symptoms of adrenal insufficiency include:
 - feeling tired or exhausted (fatigue) ○ lack of energy ○ low blood pressure (hypotension)
 - weakness ○ nausea and vomiting ○ dizziness or feeling faint
- **Increased wheezing right after taking ASMANEX HFA.** Always have a rescue inhaler with you to treat sudden wheezing.
- **Serious allergic reactions.** Stop taking ASMANEX HFA and call your healthcare provider or get emergency medical care right away if you get any of the following symptoms of a serious allergic reaction:
 - rash ○ hives ○ swelling, including swelling of the face, mouth, and tongue ○ breathing problems
- **Lower bone mineral density.** This may be a problem for people who already have a higher chance for low bone density (osteoporosis).
- **Slowed growth in children.** A child's growth should be checked often.
- **Eye problems including glaucoma, cataracts, and blurred vision.** You should have regular eye exams while using ASMANEX HFA.

The most common side effects reported while using ASMANEX HFA include:

- inflammation of the nose and throat (nasopharyngitis)
- inflammation of the sinuses (sinusitis)
- headache
- bronchitis
- flu infection (influenza)

Other side effects: Worsening asthma or sudden asthma attacks have been reported with the use of inhaled mometasone furoate.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects with ASMANEX HFA. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ASMANEX HFA?

- Store ASMANEX HFA at room temperature between 68°F to 77°F (20°C to 25°C).
- The contents of your ASMANEX HFA are under pressure. **Do not** puncture. **Do not** use or store near heat or open flame. Storage above 120°F may cause the canister to burst.
- **Do not** throw container into fire or incinerator.
- **Keep ASMANEX HFA and all medicines out of the reach of children.**

General Information about the safe and effective use of ASMANEX HFA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ASMANEX HFA for a condition for which it was not prescribed. Do not give your ASMANEX HFA to other people, even if they have the same condition that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about ASMANEX HFA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ASMANEX HFA that was written for healthcare professionals.

For more information about ASMANEX HFA go to www.ASMANEX.com, or to report side effects call 1-877-888-4231.

What are the ingredients in ASMANEX HFA?

Active ingredient: mometasone furoate

Inactive ingredients: hydrofluoroalkane (HFA-227: 1,1,1,2,3,3,3-heptafluoropropane), ethanol and oleic acid

This Patient Information has been approved by the U.S. Food and Drug Administration.

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Read these Instructions for Use before you start using ASMANEX HFA and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or your treatment.

The parts of your ASMANEX HFA:

There are 2 main parts to your ASMANEX HFA inhaler: the metal canister that holds the medicine and the blue plastic actuator that sprays the medicine from the canister.

- The inhaler also has a pink cap that covers the mouthpiece of the actuator (**see Figure 1**). The cap from the mouthpiece must be removed before use. The inhaler contains “**120**” actuations (puffs).

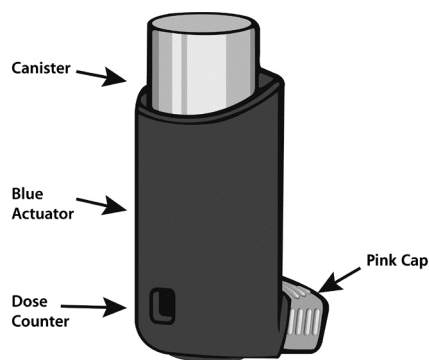


Figure 1

- The inhaler comes with a dose counter located on the plastic actuator (**see Figure 1**). The counter display will show the number of actuations (puffs) of medicine remaining. The first time you use ASMANEX HFA the dose counter will show “**124**” actuations remaining. Each time you press the canister, a puff of medicine is released and the counter will count down by **1**. The counter will stop counting at **0**.

Important Information:

- Use ASMANEX HFA exactly as your healthcare provider tells you to. Adults may assist children with using ASMANEX HFA as prescribed. Children may use ASMANEX HFA with or without a spacer device.
- **Remove the cap from the mouthpiece of the actuator before using ASMANEX HFA.**
- **Do not remove the canister from the actuator** because:
 - you may not receive the correct amount of medication.
 - the dose counter may not function properly.
 - if you try to insert the canister back into the actuator this may cause the dose counter to count down by 1 and may discharge a puff.
- Use the ASMANEX HFA canister only with the actuator supplied with the product. **Do not** use parts of the ASMANEX HFA inhaler with parts from any other inhalation medicine.

Before using your ASMANEX HFA:

Remove the cap from the mouthpiece of the actuator before using ASMANEX HFA (see Figure 2). Check the mouthpiece for objects before use. Make sure the canister is fully inserted into the actuator.

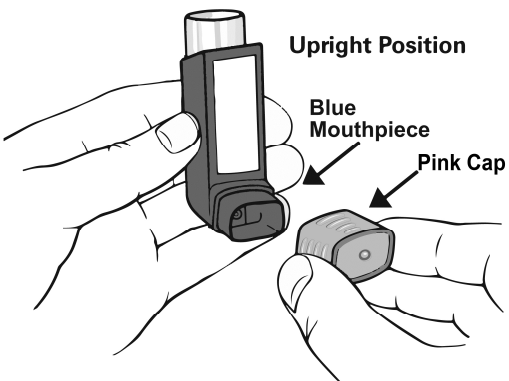


Figure 2

Priming your ASMANEX HFA Inhaler:

Before you use ASMANEX HFA for the first time, you must prime the inhaler.

1. To prime the inhaler, hold it in the upright position away from your face, and press down firmly and fully on the top of the canister until it stops moving in the actuator. Do this **4** times to release a total of **4** actuations (puffs) into the air.
2. Shake the inhaler well before each of the priming actuations. After priming **4** times, the dose counter should read “**120**”.
3. **If you do not use your ASMANEX HFA for more than 5 days, you will need to prime it again before use.**

Using your ASMANEX HFA:

4. Confirm that the strength indicated on the actuator and canister labels matches the prescribed dosage.
5. **Remove the cap from the mouthpiece of the actuator (see Figure 3).** Check the mouthpiece for objects before use. Make sure the canister is fully inserted into the actuator.
6. Shake the inhaler well before each use.
7. Breathe out as fully as you comfortably can through your mouth. Push out as much air from your lungs as possible. Hold the inhaler in the upright position and place the mouthpiece into your mouth (**see Figure 4**). Close your lips around the mouthpiece.

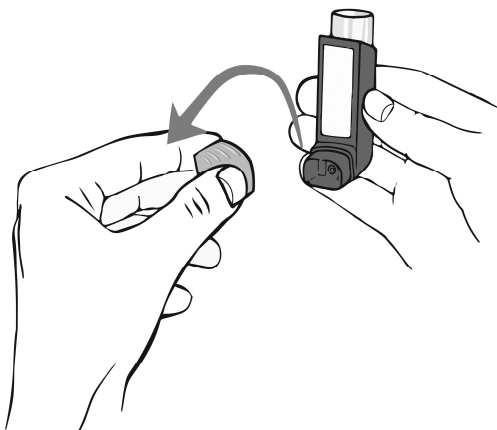


Figure 3

FOR ORAL INHALATION ONLY

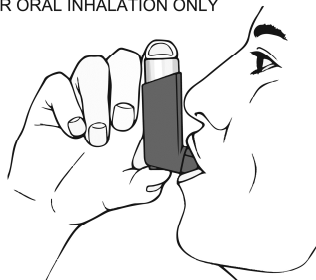


Figure 4

8. Take a deep breath (inhale) in slowly through your mouth. While doing this, press down firmly and fully on the top of the canister until it stops moving in the actuator. Take your finger off the canister.

9. When you have finished breathing in, hold your breath as long as you comfortably can, up to **10 seconds**. Then remove the inhaler from your mouth and breathe out through your nose, while keeping your lips closed.
10. Wait at least **30 seconds** to take your second puff of ASMANEX HFA.
11. Shake the inhaler well again and repeat steps 6 through 8 to take your second puff of ASMANEX HFA.

After using your ASMANEX HFA inhaler:

12. Replace the cap over the mouthpiece right away after use (see **Figure 5**).

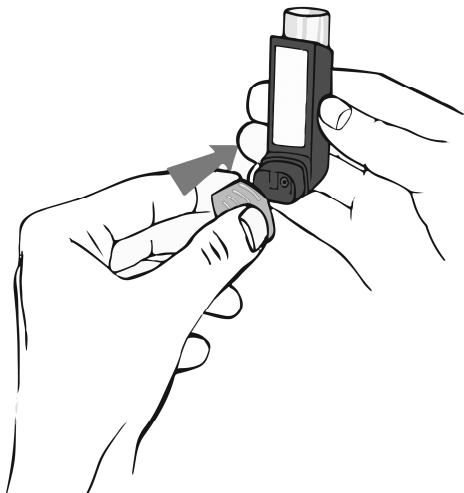


Figure 5

13. After you finish taking ASMANEX HFA (**2 puffs**), rinse your mouth with water.

Reading the counter:

- The dose counter identifies the number of inhalations (puffs) left in your inhaler (see **Figure 6**).
- The counter will count down each time you release a puff of medicine (either when preparing your ASMANEX HFA inhaler for use or when using the medicine).



Figure 6

When to replace your ASMANEX HFA:

- It is important that you pay attention to the number of inhalations (puffs) left in your ASMANEX HFA inhaler by reading the counter.

- When the counter reads “**20**”, you should refill your prescription or ask your healthcare provider if you need a new prescription for ASMANEX HFA.
- Throw away ASMANEX HFA 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.
- Do not use the inhaler after the expiration date.

How to clean your ASMANEX HFA:

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.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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For patent information: www.merck.com/product/patent/home.html

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