

Patient Information

ASMANEX[®] TWISTHALER[®] 220 mcg (mometasone furoate inhalation powder)
ASMANEX[®] TWISTHALER[®] 110 mcg (mometasone furoate inhalation powder)

FOR ORAL INHALATION ONLY

Please read this leaflet carefully before taking ASMANEX[®] TWISTHALER[®]. This leaflet does not contain the complete information about this medication. If you have any questions about ASMANEX TWISTHALER, ask your health care provider or pharmacist.

IMPORTANT POINTS TO REMEMBER ABOUT ASMANEX TWISTHALER

- Your health care provider has prescribed ASMANEX TWISTHALER for you or your child. It contains a medicine called mometasone furoate, which is a man-made corticosteroid. This medicine is used as maintenance treatment that helps prevent and control asthma symptoms.
- ASMANEX TWISTHALER is not a bronchodilator and should not be used for sudden symptoms of shortness of breath. Use an inhaled short-acting bronchodilator such as albuterol to relieve sudden symptoms of shortness of breath.
- Your health care provider may prescribe bronchodilators such as albuterol for emergency relief if an acute asthma attack occurs.
- Use your ASMANEX TWISTHALER regularly and at the same time each day, as prescribed by your health care provider. You or your child may not get the most benefit for 1 to 2 weeks or longer after starting ASMANEX. If you or your child's symptoms do not improve in that time frame or if your condition gets worse, contact your health care provider.
- The cap is needed to use the ASMANEX TWISTHALER. Do not twist the mouthpiece with your hand. When the cap is removed from the TWISTHALER, the dose counter will count down by one, and show the number of doses available after this use.
- The inhaler delivers your medicine as a very fine powder that **you or your child may not taste, smell, or feel**. Do not take or give extra doses unless your health care provider has told you to.
- It is important to replace the cap after each inhalation to protect the inhaler from moisture.
- Do not use the inhaler if you notice that it is not working correctly. Take it to your health care provider or pharmacist.

WHO SHOULD NOT USE ASMANEX TWISTHALER

Do not use ASMANEX TWISTHALER:

- To treat sudden, severe symptoms of asthma.
- If you have an allergy to milk proteins. Ask your health care provider if you are not sure.

HOW TO USE ASMANEX TWISTHALER OR GIVE TO YOUR CHILD

- **Remove the ASMANEX TWISTHALER from its foil pouch and write the date on the cap label.**
- **Throw away the inhaler 45 days after this date or when the dose counter reads "00", indicating the final dose has been inhaled, whichever comes first.**
- **Follow steps 1 and 2 below each time you inhale a dose from your ASMANEX TWISTHALER.**

Inhaler Parts:

See Figures 1 and 2 below to become familiar with the inhaler parts.



Figure 1: Inhaler (upright position)

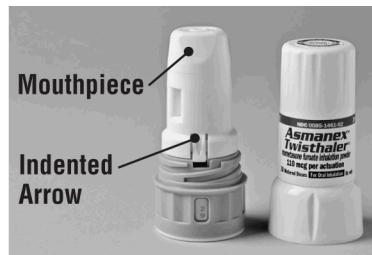


Figure 2: Inhaler with Cap Removed

Step 1: Open inhaler

Hold the inhaler straight up (upright position) with the colored portion (the base) on the bottom (see *Figure 3 below*). It is important that you remove the cap of the TWISTHALER while it is in this upright position to make sure that you get the right amount of medicine with each dose.

Holding the colored base, twist the cap in a counterclockwise direction to remove it (see *Figure 3 below*). As you lift off the cap, the dose counter on the base will count down by one. Removing the cap loads the TWISTHALER with the medicine that you are now ready to inhale.

Hold inhaler in upright position. To open, twist the cap in a counterclockwise direction.

Cap
Cap removal loads dose

Ventilation Hole

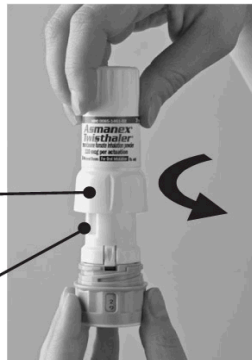


Figure 3: Cap Removal Loads Dose

IT IS IMPORTANT TO NOTE that the indented arrow (located on the white portion of the TWISTHALER, directly above the colored base) is pointing to the dose counter (see *Figure 2*).

Step 2: Inhale dose

Breathe out fully. Then bring the TWISTHALER up to your mouth or your child's mouth with the mouthpiece facing toward you or your child. Place the mouthpiece in your mouth or your child's mouth, holding it in a horizontal (on its side) position as shown below (see *Figure 4*). Firmly close your lips around the mouthpiece and take in a fast, deep breath. Since the medicine is a very fine powder, you may not be able to taste, smell, or feel it after inhalation. Do not cover the ventilation holes while inhaling the dose.

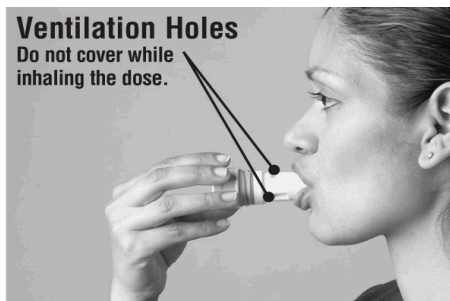


Figure 4: Inhalation

Remove the TWISTHALER from your mouth and hold your breath for about 10 seconds, or as long as you comfortably can.

IMPORTANT: DO NOT BREATHE OUT (EXHALE) INTO THE INHALER.

After you take your medicine, it is important that you wipe the mouthpiece dry, if needed, and then **REPLACE THE CAP**, firmly closing the TWISTHALER right away (see *Figures 5 and 6 below*).

Be sure that the indented arrow is in line with the dose counter. Put the cap back onto the inhaler and turn it in a clockwise direction, as you gently press down. You'll hear a "click" to let you know that the cap is fully closed. This is the only way to be sure that your next dose is loaded the right way.

**Indented Arrow
should line up with
Dose Counter.**

**Replace cap and
turn clockwise
until "click".**

Indented Arrow
Dose Counter

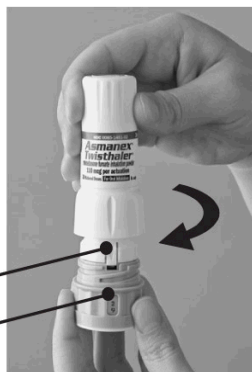


Figure 5: Closing the Inhaler

**You'll hear a "click"
to let you know
that the cap is
fully closed.**

**This is the only
way to be sure that
your next dose is
properly loaded.**



Figure 6: Closed Inhaler

IT IS IMPORTANT TO REPEAT STEPS 1 AND 2 EACH TIME YOU INHALE.

Rinse your mouth after using.

STORING YOUR INHALER

- Keep your inhaler clean and dry at all times. If the mouthpiece needs cleaning, gently wipe the mouthpiece with a dry cloth or tissue as needed. Do not wash the inhaler. Avoid contact with any liquids.
- **Store in a dry place at 25°C (77°F) [may range between 15-30°C (59-86°F)].**
- Keep your inhaler out of the reach of children.

HOW TO KNOW WHEN YOUR INHALER IS EMPTY

The inhaler has a dose counter on the colored base, which shows the number of doses left to use. As you lift off the cap to take your dose, the dose counter on the base will count down by one (if you began with the dose counter reading “30” this will cause the dose counter to now read “29”). Read the numbers from top to bottom.

When the unit reads “01” this indicates the last remaining dose. After dose “01” the counter will read “00”. When you replace the cap, the unit will lock and then must be thrown away. Start using a new ASMANEX TWISTHALER as instructed by your health care provider.

BEFORE AND DURING TREATMENT WITH ASMANEX TWISTHALER

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

ASMANEX TWISTHALER may affect the way other medicines work, and other medicines may affect how ASMANEX TWISTHALER 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, and cobicistat-containing products.

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.

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

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

POSSIBLE SIDE EFFECTS WITH ASMANEX TWISTHALER

Serious Side Effects may include:

- **Fungal infections in the mouth and throat.** Patients who use inhaled steroid medicines for asthma may develop a fungal infection of the mouth. Rinse your mouth after using ASMANEX TWISTHALER.
- Worsening asthma or sudden asthma attacks
- **Serious allergic reactions.** Call your health care provider or get emergency medical care if you get any symptoms of a serious allergic reaction, including:
 - Rash
 - Swelling of the face, mouth and tongue
 - Breathing problems

• **Possible increased risk of infection due to a weakened immune system with using steroid medicines.** Tell your health care provider if you or your child have or had TB, are exposed to anyone with chickenpox or measles, or about any other infections you or your child had before or while using ASMANEX TWISTHALER.

• **Adrenal insufficiency (your adrenal gland cannot produce enough steroids since you were on oral steroid medicine).** If you or your child took steroids by mouth and are having them decreased (tapered) or you are being switched to ASMANEX TWISTHALER, you should be followed closely by your health care professional.

Death can occur. Tell your health care professional right away about any symptoms such as feeling tired or exhausted, weakness, nausea, vomiting, or symptoms of low blood pressure (such as dizziness or faintness). If you or your child is under stress, such as with surgery, after surgery or trauma, you may need steroids by mouth again.

• **Decreased bone mass (bone mineral density).** Patients who use inhaled steroid medicines for a long time may have an increased risk of decreased bone mass, which can affect bone strength. Talk with your health care provider about any questions about bone health.

• **Glaucoma, cataract, and visual disturbance.** Contact your doctor if you experience blurred vision or other changes in your vision.

The most common side effects with ASMANEX TWISTHALER include: headache, nasal allergy symptoms, sore throat, upper respiratory tract infection, sinus infection, fungal infections in the mouth, painful menstrual periods, muscle and bone pain, back pain, and upset stomach.

Tell your health care professional about any side effects that bother you or do not go away. These are not all of the possible side effects with ASMANEX TWISTHALER. For more information, ask your health care professional.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

Manufactured by:
MSD International GmbH (Singapore Branch)
Singapore 638030, Singapore

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

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