

PART III: CONSUMER INFORMATION**ASMANEX[®] Twisthaler[®]**

Mometasone Furoate Dry Powder Inhaler

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

ABOUT THIS MEDICATION**What the medication is used for:**

ASMANEX[®] Twisthaler[®] is an inhaled corticosteroid medicine for the long-term treatment of asthma in people aged 4 years and older.

- ASMANEX[®] Twisthaler[®] helps to prevent and control symptoms of asthma.
- ASMANEX[®] Twisthaler[®] does not treat the sudden symptoms of an asthma attack, such as wheezing, cough, shortness of breath, and chest pain or tightness. Always have a fast-acting bronchodilator medicine (rescue inhaler) with you to treat sudden symptoms.

What it does:

ASMANEX[®] Twisthaler[®] contains mometasone furoate, an inhaled corticosteroid (ICS). It reduces inflammation in the airways of the lungs, which can ease breathing problems.

Regular use of ASMANEX[®] Twisthaler[®] will not cure your asthma but will help prevent and control your asthma symptoms.

When it should not be used:**Do not use ASMANEX[®] Twisthaler[®]:**

- If you are allergic to mometasone furoate or to any other corticosteroid medicine, or to lactose.
- To treat a sudden attack of breathlessness.
ASMANEX[®] Twisthaler[®] is not a rescue inhaler and should not be used to give you fast relief from your asthma attack. Always use a rescue inhaler, such as salbutamol, during a sudden asthma attack. You should always carry the bronchodilator 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 lungs.
- If you have herpes simplex infection in the eye.

What the medicinal ingredient is:

Mometasone furoate

What the nonmedicinal ingredients are:

Lactose anhydrous (which contains trace amounts of milk proteins).

What dosage forms it comes in:

Dry powder for oral inhalation

- ASMANEX[®] Twisthaler[®] 100 mcg/metered inhalation
- ASMANEX[®] Twisthaler[®] 200 mcg/metered inhalation
- ASMANEX[®] Twisthaler[®] 400 mcg/metered inhalation

Each inhaler is supplied in a protective foil pouch with a *Consumer Information* leaflet.

WARNINGS AND PRECAUTIONS**BEFORE YOU USE ASMANEX[®] Twisthaler[®], talk to your doctor if you:**

- have ever had to stop taking other medicines for asthma because you were allergic to them, or had other problems with them.
- are presently taking other corticosteroid medicines, either by the mouth, by injection, or by inhalation.
- have or have ever had tuberculosis (TB).
- have herpes infection of the eye or any other type of untreated infection.
- have a fungal infection (thrush) in your mouth or throat.
- are taking any other medicines, even those not prescribed.
- have glaucoma or are at risk of developing glaucoma.
- have a problem with your thyroid or adrenal glands.
- have hypoprothrombinemia and are taking acetylsalicylic acid.
- are pregnant, plan to become pregnant or breast-feeding a baby.
- have a problem with your liver.

Important things to remember when using ASMANEX[®] Twisthaler[®]:

- **Contact your doctor immediately if you have an asthma attack that does not improve after you use your rescue inhaler during treatment with ASMANEX[®] Twisthaler[®]. Your doctor may change your dose or your medicine.**

- **Contact your doctor immediately if you think you are having an allergic reaction to ASMANEX[®] Twisthaler[®] (wheezing or difficulty in breathing shortly after taking this medicine).**

- **Do not stop taking ASMANEX[®] Twisthaler[®] suddenly. Speak with your doctor first.** You need to lower the amount you take slowly before stopping the medication completely.

- Avoid exposure to chicken pox and measles, and notify your doctor if you or your child are exposed. This is important if you are taking any cortisone-type medicine and your immune system is not functioning well (if you have difficulty in fighting infection).

- All cortisone-type medicines, especially when used for a long time, may possibly interfere with the usual growth pattern in growing children and adolescents. You may want to discuss this with your doctor.

- When using drugs like ASMANEX[®] Twisthaler[®] 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 ASMANEX[®] Twisthaler[®] 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.

- You may need to also take steroid pills or syrup during a severe asthma attack, during other illnesses or during times of stress.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with ASMANEX[®] Twisthaler[®]. Your doctor may wish to monitor you carefully if you are taking these medicines:

- Ketoconazole (used to treat fungal infections)
- Itraconazole,
- Clarithromycin,

- Ritonavir,
- Cobicistat-containing products

PROPER USE OF THIS MEDICATION

HOW TO USE ASMANEX[®] Twisthaler[®]

Your doctor has determined the correct dose of this medicine. Your doctor will instruct you how often to use this medicine, depending on relief of your symptoms. Your doctor may adjust this dose, depending on your response to treatment.

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

Usual Dose:

Adults and Adolescents (12 years of age and older)

The recommended dose is 200 mcg or 400 mcg administered by oral inhalation once a day in the evening.

Asthma control is better achieved if once daily dosing is administered in the evening.

For patients previously on high doses of inhaled corticosteroids, 200 mcg given twice a day may provide better asthma control.

Your doctor will try to find the lowest dose that will control your asthma. If your asthma is well controlled with 400 mcg once a day, your doctor may reduce this dose to 200 mcg once a day. As your dose is lowered, your doctor will prescribe a different formulation of this product. Then, depending on your response to treatment, your doctor may need to increase your daily dose to determine the best dose to keep your symptoms under control.

Patients who are also taking oral corticosteroids:

The recommended starting dose of ASMANEX[®] Twisthaler[®] is 400 micrograms twice daily by inhalation. This is a total of 800 mcg per day.

The maximum dose is 800 mcg per day.

After approximately one week of ASMANEX[®] Twisthaler[®] treatment, your doctor may start to lower the dose of the other corticosteroid very slowly. Eventually, it may be possible to lower the dose of ASMANEX[®] Twisthaler[®], as well. This must be done only under medical supervision.

Pediatric patients (4 to 11 years of age)

The recommended dose is 100 mcg administered by oral inhalation once daily in the evening.

Use ASMANEX® Twisthaler® regularly and at the same time each day, as prescribed by your doctor. Some patients may experience relief within 24 hours, although you or your child may not get the most benefit for 1 to 2 weeks or longer after starting ASMANEX® Twisthaler®. If you or your child's symptoms do not improve in that time frame or if your condition gets worse, contact your doctor.

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 doctor has told you to.

Do not take more doses of ASMANEX® Twisthaler® or use your inhaler more often than your doctor advises.

If you also use an inhaled bronchodilator in another inhaler, you should take the bronchodilator before you take ASMANEX® Twisthaler®. You should wait a few minutes between taking each inhaler.

Patient's Instructions for Use

Remove the ASMANEX® Twisthaler® from its foil pouch and write the date on the cap label.

Throw away the inhaler 2 months 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.

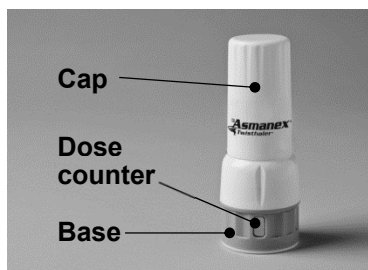


Figure 1 Inhaler (upright position)

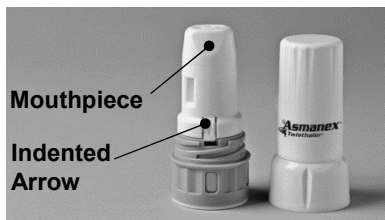


Figure 2 Inhaler with Cap Removed

How to Use

1. Open inhaler

To open the inhaler, remove the cap as follows: Hold the inhaler straight up (upright position) with the colored portion, or base (maroon; 400 mcg/metered inhalation, pink; 200 mcg/metered inhalation or grey; 100 mcg/metered inhalation) down as shown (**Figure 3**).

Hold the colored base and twist the cap counterclockwise to remove it (**Figure 3**). As you lift off the cap, the dose counter on the base will count down by one.

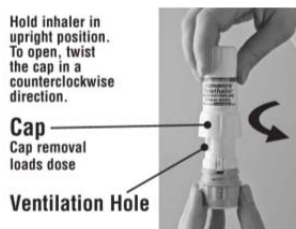


Figure 3 Cap Removal Loads the Dose

The counter on the colored base and the pointer on the body above the counter should be in line with one another.

Removing the cap loads the inhaler with the medicine that you are now ready to inhale. Keep the inhaler upright once the cap is removed and prior to inhaling your dose.

2. Inhale dose

a) Breathe out fully.

b) Bring the inhaler up to your mouth or your child's mouth with the mouthpiece pointing toward you or your child. Place the mouthpiece in your mouth or your child's mouth in a horizontal (on its side) position as shown below (**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 or your child may not be able to taste, smell or feel it after

inhalation. Do not cover the ventilation holes while inhaling the dose.

c) Remove the inhaler from your mouth or your child's mouth and hold your breath or have your child hold their breath for about 10 seconds, or for as long as is comfortable (**Figure 4**).



Figure 4 Inhalation

Do not breathe out (exhale) into the inhaler.

3. Close the inhaler

After you take your medicine it is important that you wipe the mouthpiece with a dry cloth or tissue (do not wash the inhaler; avoid any contact between the inhaler and water) and replace the cap, firmly closing the inhaler right away (**Figures 5 and 6 below**).

The cap must be fully replaced and rotated to load the dose for the next inhalation. Put the cap back onto the inhaler and turn the cap clockwise while gently pressing the cap down until a click sound is heard and the cap is fully closed (**Figure 5**). This is the only way to be sure that your next dose is loaded the right way. The arrow on the cap should be fully aligned with the counter window (**Figure 6**).

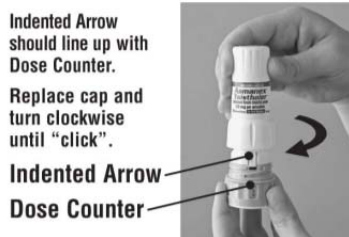


Figure 5 Closing the inhaler

It is important to repeat steps 1–3 if your doctor has prescribed more than one inhalation.

Rinse your mouth or your child's mouth after inhalation.

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

Do not use ASMANEX[®] Twisthaler[®] if you notice that the metered counter is not working correctly. See your doctor or pharmacist.

How To Know When Your Inhaler Is Empty

The inhaler has a dose counter window on the colored base. It is a digital display which shows the number of doses remaining. When the counter reads '01', this indicates the last remaining dose. After dose '01', the counter will read '00', and the cap will lock. Throw away the inhaler. Start using a new ASMANEX[®] Twisthaler[®] as instructed by your doctor.

Overdose:

If you have used the inhaler more than you were instructed to, talk to a doctor or pharmacist immediately.

If you have used larger doses for a long period of time, talk to your doctor or pharmacist for advice. You will need to lower your dose gradually. Do not stop taking the medication suddenly.

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

Missed Dose:

It is **VERY IMPORTANT THAT YOU USE ASMANEX[®] Twisthaler[®] REGULARLY**; however, if you miss a single dose, do not worry – just take the next dose when it is due.

Your symptoms may return if you stop using **ASMANEX[®] Twisthaler[®]** earlier than your doctor has prescribed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

POSSIBLE SIDE EFFECTS

Adults and Adolescents 12 years of age and older

- Swollen, sore, irritated or inflamed throat, dry mouth or throat, or increased production of saliva,
- Loss of voice or hoarseness, inability to speak, painful or burning feeling of the tongue,
- Blocked nose, runny nose, polyps, or nose bleeds. Inflammation of the nose and allergy symptoms,
- Red or itchy eyes,
- Ear pain,
- Cough, sneezing, prolonged expiration,
- Nausea, stomach ache, diarrhea, constipation, decreased appetite, thirst,
- Muscle, neck or back pain, pain in muscles/bones in the chest area, arthritis, muscle/joint stiffness,
- Headache, migraine, dizziness, depression, fatigue, stress, physical or emotional symptoms before menstruation,
- Rash, hives, skin chafing, itching, skin bruising, increased sweating,
- Irregular uterine bleeding.

Children 4 to 11 years of age

The most common adverse events seen in patients treated with 100 mcg once daily in the evening were:

- Fever
- Stomach ache
- Vomiting

The following side effects are associated with corticosteroid use:

- Increased pressure in the eye (including glaucoma) or cataracts,
- Decreased bone mass,
- Bone fractures/osteoporosis:
In situations where healthy people would not normally break a bone you may have sudden pain in any location and especially in the wrist, spine or hip. This may be a fracture.
- Slowed growth in children and adolescents. It is recommended that children being treated with steroids, including ASMANEX[®] Twisthaler[®] have their height checked regularly by their doctor.

ASMANEX[®] Twisthaler[®] can cause abnormal blood test results, e.g., increased liver enzymes, decreased platelets. Your doctor will decide when to perform blood tests and will interpret the results.

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 medical help
	Only if severe	In all cases	
Common			
Thrush (yeast infection): White patches in the mouth and tongue, sore throat		√	
Rare			
Serious allergic reactions: rash, swelling of the face, mouth, lips and tongue, breathing problems			√
Worsening asthma or sudden asthma attacks: cough, difficulty breathing, and wheezing			√
Increased heart rate, chest pain			√
Respiratory distress: difficulty breathing	√		
Decreased Platelets: bruising, bleeding, fatigue and weakness		√	
Unknown			
Decreased Adrenal Function: Tiredness, weakness, nausea and vomiting, low blood pressure		√	
Glaucoma: Increased pressure in your eyes and/or eye pain		√	
Cataract: Clouding of the lens in the eyes, blurry vision, and/or eye pain		√	
Central Serous Chorioretinopathy (CSCR): Distorted vision/blurry vision		√	
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,		√	

This is not a complete list of side effects. For any unexpected effects while taking ASMANEX[®] Twisthaler[®], contact your doctor or pharmacist.

HOW TO STORE IT

Store in a dry place at room temperature, 15 to 30 °C. Do not use after the date shown on the inhaler or beyond 2 months after removal from the foil pouch.

Keep your inhaler out of the reach and sight of children.

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), or
- 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

If you want more information about ASMANEX[®]:

- 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 or Merck Canada website (www.merck.ca) or by calling Merck Canada at 1-800-567-2594

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