

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

ASMANEX[®] Twisthaler[®] **Mometasone Furoate Dry Powder Inhaler**

Read this carefully before you start taking **ASMANEX[®] Twisthaler[®]** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ASMANEX[®] Twisthaler[®]**.

What is ASMANEX[®] Twisthaler[®] used for?

ASMANEX[®] Twisthaler[®] is an inhaled corticosteroid medicine. It is 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 rescue inhaler (fast-acting bronchodilator medicine) with you to treat sudden symptoms.

How does ASMANEX[®] Twisthaler[®] work?

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.

What are the ingredients in ASMANEX[®] Twisthaler[®]?

Medicinal ingredients: Mometasone furoate

Non-medicinal ingredients: Lactose anhydrous (which contains trace amounts of milk proteins).

ASMANEX[®] Twisthaler[®] comes in the following dosage forms:

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 *Patient Medication Information* leaflet.

Do not use ASMANEX[®] Twisthaler[®] if:

- you are allergic to mometasone furoate, milk proteins, lactose or any other non-medicinal components of this product.
- you have 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.
- you have an untreated infection (fungal, bacterial, viral or parasitic).
- you have tuberculosis infection of the lungs.
- you have herpes simplex infection in the eye.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ASMANEX® Twisthaler®. Talk about any health conditions or problems you may have, including 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 or previously took other corticosteroid medicines (e.g. prednisone, dexamethasone) either by mouth, injection, or inhalation.
- take drugs that suppress your immune system, or if you have a problem with your immune system.
- have or have ever had tuberculosis (TB).
- have a fungal infection (thrush) in your mouth or throat (white patches in the mouth or sore throat).
- have glaucoma or are at risk of developing glaucoma.
- have a problem with your thyroid or adrenal glands.
- have a rare blood disorder called hypoprothrombinemia and are taking acetylsalicylic acid.
- have a problem with your liver.
- are pregnant, plan to become pregnant or are breast-feeding a baby.

Other warnings you should know about:

- Contact your healthcare professional immediately if you:
 - have been taking ASMANEX® Twisthaler® and experience an asthma attack (e.g.: wheezing) that does not improve after you use your rescue inhaler.
 - need to also take steroid pills or syrup during a severe asthma attack.
 - 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.
- ASMANEX® Twisthaler® can cause abnormal blood test results. Your healthcare professional may monitor:
 - your blood (e.g.: for increased liver enzymes or decreased platelets)
 - the function of certain glands
- ASMANEX® Twisthaler® and other corticosteroids can suppress the immune system. Avoid exposure to chicken pox and measles and tell your healthcare professional if you are exposed.
- All cortisone-type medicines, especially when used for a long time, may possibly interfere with the usual growth pattern in growing children and adolescents. Your healthcare professional will monitor the height of your child/adolescent often if they are being treated with ASMANEX® Twisthaler® for a long time.
- 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;

Therefore, make sure you have regular eye exams.

- Transfer from oral corticosteroids to ASMANEX[®] Twisthaler[®]:
 - Your healthcare professional will guide you through the process of transferring from an oral corticosteroid to ASMANEX[®] Twisthaler[®]. This needs to be done slowly and with medical supervision to help you avoid side effects.
 - You may still need to take oral corticosteroids to help you during a severe asthma attack or times of illness or stress.
 - Carry a supply of oral corticosteroids and a warning card that explains that you may need to take oral corticosteroids during stress or a severe asthma attack.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ASMANEX[®] Twisthaler[®]:

- drugs used to treat fungal infections (ketoconazole, itraconazole)
- drugs used to treat bacterial infections (clarithromycin)
- drug used in HIV/AIDS treatment (atazanavir, indinavir, nelfinavir, saquinavir, ritonavir, cobicistat-containing products).

How to take ASMANEX[®] Twisthaler[®]:

- Your healthcare professional will:
 - decide the best dose for you and will tell you how often to take it.
 - try to find the lowest dose that will control your asthma. This means that your dose may be adjusted up or down depending on your response to treatment.
- Use ASMANEX[®] Twisthaler[®] at the same time each day even if you don't have any symptoms. If you are using ASMANEX[®] Twisthaler[®] once daily, asthma control is better if you take your dose in the evening.
- You may feel relief within 24 hours.
- You may not get the most benefit for 1 to 2 weeks or longer after starting ASMANEX[®] Twisthaler[®]. If your symptoms do not improve in that period, or if your condition gets worse, talk to your healthcare professional.
- Do not use your inhaler more often than your healthcare professional advises.
- If you also use a bronchodilator, use your bronchodilator **before** you use ASMANEX[®] Twisthaler[®]. Wait a few minutes between using each inhaler.
- Do not stop using ASMANEX[®] Twisthaler[®] suddenly. Your treatment should be decreased slowly, under the supervision of your healthcare professional.
- As prescribed by your healthcare professional, you should always carry a rescue inhaler such as salbutamol with you. Use your rescue inhaler if your asthma symptoms occur

between doses of ASMANEX[®] Twisthaler[®]. If your rescue inhaler medication becomes less effective, seek medical attention right away.

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.

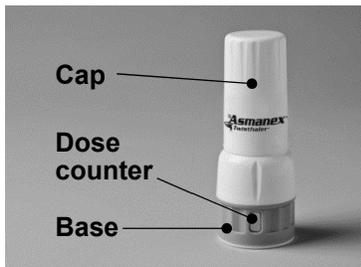


Figure 1 Inhaler (upright position)

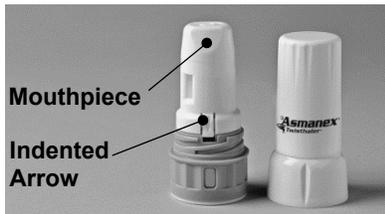


Figure 2 Inhaler with Cap Removed

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 in **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.

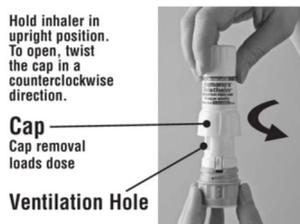


Figure 3 Cap Removal Loads the Dose

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 when you remove the cap and prior to inhaling your dose.

2. Inhale dose

a) Breathe out fully.

b) Bring the inhaler up to your mouth with the mouthpiece pointing toward you. Making sure not to cover the ventilation holes, place the mouthpiece in your 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 may not be able to taste, smell or feel it after inhalation.

c) Remove the inhaler from your mouth and hold your 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**).

Replace the cap and rotate it 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. Align the arrow on the cap with the counter window (**Figure 6**).

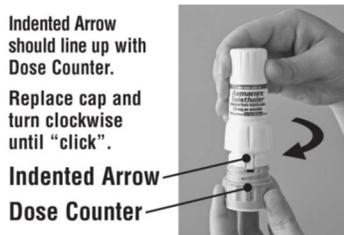


Figure 5 Closing the inhaler

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

Rinse your mouth after inhalation and spit out the contents without swallowing.



Figure 6 Closed Inhaler

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

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 healthcare professional.

Usual dose:

Adults and Adolescents (12 years of age and older)

The recommended dose is 200 mcg or 400 mcg taken by oral inhalation once daily in the evening.

Patients who are also taking oral corticosteroids:

The recommended starting dose of ASMANEX[®] Twisthaler[®] is 400 micrograms twice daily (800 mcg) by inhalation.

The maximum dose is 800 mcg per day.

After about one week of ASMANEX[®] Twisthaler[®] treatment, your doctor may start to lower the dose of the other corticosteroid very slowly.

Pediatric patients (4 to 11 years of age):

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

Overdose:

If you have used the inhaler more than you were instructed to, talk to a healthcare professional immediately.

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

If you think you have taken too much ASMANEX[®] Twisthaler[®], contact your healthcare professional, 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 healthcare professional has prescribed.

What are possible side effects from using ASMANEX[®] Twisthaler[®]?

These are not all the possible side effects you may feel when taking ASMANEX[®] Twisthaler[®]. If you experience any side effects not listed here, contact your healthcare professional.

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get 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			√
Bone fractures/osteoporosis (thin, fragile bones): broken bones, pain, especially wrist, spine or hip pain that gets worse when standing or walking		√	
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		√	
Increased Liver Enzymes: dark urine, fatigue, loss of appetite, yellowing of the skin or eyes		√	
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/blurred 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		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

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 out of reach and sight of children.

If you want more information about ASMANEX[®] Twisthaler[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp> or the Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

Last revised: April 21, 2021

© N.V. Organon. Used under license.

© 2021 Organon Canada Inc. All rights reserved.