

Package Leaflet: Information for the user

Asmanex® Twisthaler® 400 micrograms Inhalation Powder mometasone furoate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Asmanex Twisthaler is and what it is used for
2. What you need to know before you use Asmanex Twisthaler
3. How to use Asmanex Twisthaler
4. Possible side effects
5. How to store Asmanex Twisthaler
6. Contents of the pack and other information

1. What Asmanex Twisthaler is and what it is used for

Asmanex Twisthaler contains the active substance mometasone furoate, which belongs to a group of medicines called corticosteroids or steroids as they are simply known.

Corticosteroids should not be confused with “anabolic” steroids that are misused by some athletes. Corticosteroids are used to prevent asthma attacks because they have an anti-inflammatory effect. They reduce swelling and irritation in the walls of the small air passages in the lungs. This helps to ease breathing problems.

Asmanex Twisthaler is used regularly to control asthma in adults and adolescents, aged 12 years and over. It can be used if you have not used a steroid before and your asthma is not controlled by other medicines. It can also be used if you have been taking a different steroid either by mouth or by inhalation, to control your asthma. Used regularly Asmanex Twisthaler will help to control asthma and prevent asthma attacks. It is a “preventor”. Do not use this medicine for a sudden asthma attack. You should always carry the bronchodilator (“reliever inhaler”) that your doctor has prescribed, just in case you have an asthma attack.

2. What you need to know before you use Asmanex Twisthaler

Do not use Asmanex Twisthaler

- if you are allergic to mometasone furoate, to any other steroid or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Asmanex Twisthaler if:

- you have or have ever had tuberculosis (TB).
- you have herpes simplex (virus) infection of the eye or any other type of infection.

- you develop thrush (white patches in your mouth or on your throat) as this may need treatment. Your doctor may also tell you to stop using Asmanex Twisthaler for a while or may decide to treat you with a different type of inhaler. Rinsing your mouth with water or a mouthwash solution and then spitting this out without swallowing after you have finished taking your dose will help to prevent thrush.

Contact your doctor if you experience blurred vision or other visual disturbances.

Important things to remember when using Asmanex Twisthaler

- Get medical help immediately if you start wheezing or have difficulty breathing shortly after using Asmanex. These symptoms may be an “allergic” reaction to this medicine.
- You should always have a bronchodilator inhaler (a 'reliever' inhaler) with you to quickly relieve the symptoms of an asthma attack (such as coughing, wheezing and tightening of the chest).
- If you have an asthma attack and the attack does not improve after you use a ‘reliever’ inhaler or if your peak flow measurement falls (your doctor will tell you the peak flow numbers that are right for you), you should get medical help straight away. Tell your doctor as your asthma may be getting worse and you may need to change your medicine.
- 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.
- If you are taking Asmanex and reducing the dose of steroid tablets or syrup you take, you may start to get symptoms such as itchy, watery eyes or rash, which were controlled before. 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, you should tell your doctor.
- While using inhaled corticosteroids, patients should avoid coming into contact with anyone who has measles or chicken pox. If you do come into contact with anyone who has either of these infections tell your doctor. This is particularly important for children.
- Treatment with medicines like Asmanex Twisthaler may alter the normal levels of steroids in your body. One effect of this might be that adolescents being treated for a long time might grow more slowly. Your doctor will probably check your height from time to time.
- All steroids, especially when used for a long time, may alter the way your adrenal gland works. Your doctor can carry out a blood test to check this.
- Remember to take this medicine, and any others that you are taking, with you if you have to go into hospital.
- Your doctor may test your lungs during your treatment, especially if you are about to stop taking corticosteroid tablets.

Children and adolescents

There are no data available and should not be used in children less than 12 years of age.

Other medicines and Asmanex Twisthaler

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. This also includes medicines to treat a fungal or viral infection, such as ketoconazole, itraconazole, ritonavir, nelfinavir or cobicistat. These medicines can increase the amount of steroid in your blood.

Some medicines may increase the effects of Asmanex Twisthaler and your doctor may wish to monitor you carefully if you are taking these medicines.

It is also important to tell your doctor before you start to use Asmanex Twisthaler if you are taking other steroids, either by injection, by mouth or inhaled. Your doctor will tell you how to adjust the dose of these other steroids.

Pregnancy and breast-feeding

Ask your doctor for advice if you are pregnant, planning to become pregnant, or if you are breast-feeding.

Driving and using machines

Asmanex Twisthaler is not likely to affect your ability to drive or use machines.

Asmanex Twisthaler contains lactose

This medicine contains a small amount of lactose (4.64 mg per day is the maximum recommended daily dose). This amount does not normally cause problems in lactose intolerant people.

3. How to use Asmanex Twisthaler

Make sure that you know how to use the Twisthaler properly. Take care not to drop the inhaler as this may cause the inhaler to malfunction. If you have any problems, ask your doctor or pharmacist. Make sure you know when and how many doses you should inhale. Your doctor should have told you and the instructions should be on the pharmacist's label. Always take this medicine exactly as your doctor or pharmacist has told you. **Do not change your dose unless your doctor has told you to.** Check with your doctor or pharmacist if you are not sure.

For adults (including patients over 65 years) and adolescents aged 12 years and over, with mild to moderate asthma, the recommended starting dose is 400 micrograms (1 dose or inhalation) once a day in the evening requiring Asmanex 400 micrograms Inhalation Powder however, for some patients the starting dose may be 200 micrograms (1 dose or inhalation) twice a day requiring Asmanex Twisthaler 200 micrograms Inhalation Powder. If your asthma is controlled, your doctor may reduce the dose to 200 micrograms (1 dose or inhalation of Asmanex Twisthaler 200 micrograms Inhalation Powder) once a day in the evening. Depending on your symptoms, your doctor may increase or decrease your daily dose to keep your asthma under control.

For patients with severe asthma who may be taking other steroid tablets or syrup, the usual starting dose of Asmanex Twisthaler is 400 micrograms twice a day, which is the highest recommended dose. After about one week of Asmanex Twisthaler treatment, your doctor may start to lower the dose of the other corticosteroid very slowly until you can stop taking it altogether. It may then be possible to lower the dose of Asmanex Twisthaler if your asthma is controlled well.

Instructions for the proper use of your inhaler

Remember that Asmanex Twisthaler produces a very fine powder, which you must inhale into your lungs. You should be upright when using your Twisthaler. Follow these instructions carefully, to receive the correct dose.

Before removing the white cap, be sure the counter and the pointer on the cap are lined up. To open the inhaler, remove the white cap. Hold the inhaler upright, with the maroon base down. Grip the base and twist the cap anticlockwise to remove it. As you remove the cap, the inhaler's dose counter will count down by one.

Ensure that the counter on the maroon base and the pointer above the counter are in line with one another. Keep the inhaler upright once the cap is removed and before inhaling your dose.

To inhale your dose,

- a) Remove the cap from your inhaler [Figure 1]
- b) Bring the inhaler up to your mouth, with the mouthpiece pointing toward you.
- c) Insert the mouthpiece of the inhaler in your mouth, close your lips around the mouthpiece, and then breathe in rapidly and deeply. [Figure 2]
- d) Remove the inhaler from your mouth and hold your breath for about 10 seconds, or for as long as is comfortable. Do not breathe out through the inhaler.
- e) To close the inhaler, replace the inhaler cap immediately after each inhalation. The cap must be fully replaced and turned to load the dose for the next inhalation. Do this by turning the cap clockwise, while gently pressing the cap down until a click sound is heard and the cap is fully closed. [Figure 3] The arrow on the cap must be fully lined up with the counter window. [Figure 4]

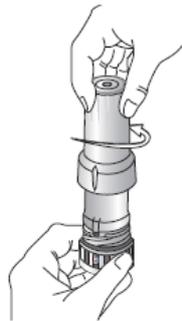


Figure 1
Cap removal

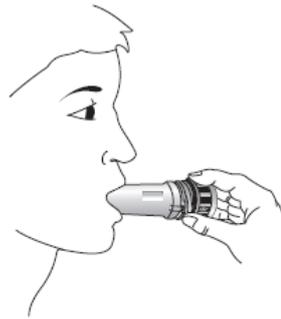


Figure 2
Inhalation

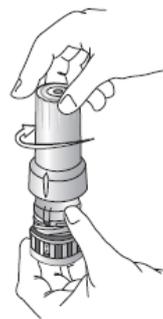


Figure 3
Closing the inhaler

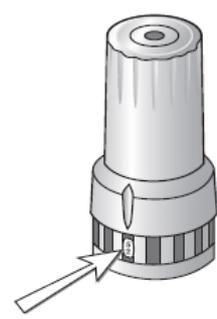


Figure 4
Closed Inhaler

After you have finished taking your dose, rinse your mouth with water or a mouthwash solution and then spit this out without swallowing. This will help to prevent thrush.

Keep your inhaler clean and dry at all times. Clean the outside of the mouthpiece with a dry cloth or tissue. Do not wash the inhaler; avoid contact with water.

At the base of the inhaler there is a window, which contains a counter. This shows the number of doses that are left in the inhaler. Do not use Asmanex Twisthaler if the counter is not working properly. Take it to your doctor or pharmacist.

When you see “01” in the counter window, this means that there is only one dose left in the inhaler. After dose 01, the counter will read “00”, the cap will lock, and you will not be able to use the inhaler again. You should then throw the inhaler away.

To make sure you always have enough medicine get a repeat prescription from your doctor before your inhaler is empty.

There is no set time for how quickly your treatment will take to work. Some patients may get some relief within 24 hours after starting treatment; others may not get the maximum benefit for one to two weeks or longer. Your doctor will tell you how long to use Asmanex Twisthaler for.

If you use more Asmanex Twisthaler than you should:

It is important that you take your dose as stated on the pharmacist’s label or as advised by your doctor. You should not increase or reduce your dose without seeking medical advice. If you accidentally take a larger dose than you were told to, tell your doctor.

If you forget to take Asmanex Twisthaler:

If you miss a dose just take the next dose when it is due. Do not take a double dose to make up for the forgotten dose.

If you stop taking Asmanex Twisthaler

Do not suddenly stop using Asmanex Twisthaler even if your asthma seems to be better. Speak with 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 Asmanex Twisthaler go back and see your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Asmanex Twisthaler and talk to your doctor immediately if you have any of the following symptoms:

Symptoms of a serious allergic reaction include swelling of your eyes, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed which may cause you to collapse.

If you notice an increase in coughing, wheezing, difficulty breathing or shortness of breath immediately after inhaling the medicine use your “reliever” inhaler and contact your doctor straightaway. You should not use Asmanex Twisthaler again until you have seen your doctor. It is possible to have allergic (hypersensitivity) reactions to inhaled steroids. If this happens you may notice skin rash, itching and redness and swelling of the eyes, face, lips and throat. If you have any of these symptoms you should contact your doctor straightaway. You should not use Asmanex Twisthaler again until you have seen your doctor.

The most commonly reported side effects include candida infection (thrush) in the mouth or throat (this appears as white patches), hoarseness, a sore throat or headache. Tell your doctor as soon as possible if you develop any of these side effects.

Other uncommon (may affect up to 1 in 100 people) side effects include dry mouth and throat, indigestion, weight increase and rapid or pounding heartbeat (palpitations). Contact your doctor if you notice any of these symptoms.

Rarely (may affect up to 1 in 1,000 people), patients using inhaled steroids, including Asmanex Twisthaler, develop increased pressure in the eye (including glaucoma) or cataracts.

Not known (frequency cannot be estimated from the available data): blurred vision.

Contact your doctor if your vision is blurry or if you have eye pain.

Other possible side effects of steroids include slowing or change in the growth pattern in adolescents and thinning of the bones. Sleeping problems, depression or feeling worried, restlessness, nervousness, excitability or irritability may also occur with the use of inhaled corticosteroids. These effects are more likely to occur in children. Steroids may also affect your adrenal gland, causing weakness, fatigue or dizziness and faintness when standing for a long time or after getting up from a sitting position. These effects are much less likely to occur when taking inhaled corticosteroids than with steroids taken by mouth.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAPharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Asmanex Twisthaler

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, foil pouch and label after {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

Do not store above 30 °C. Do not refrigerate or freeze.

Store each Twisthaler in the original package in order to protect from moisture until it is needed, and then use it within 3 months of first opening. Only open one Twisthaler at a time.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Asmanex Twisthaler contains

- The active substance is mometasone furoate. Each inhalation contains 400 micrograms.
- The only other ingredient is lactose anhydrous (which contains trace amounts of milk proteins).

What Asmanex Twisthaler looks like and contents of the pack

The inhaler mouthpiece is white, with a maroon-coloured base containing an open display window that shows the number of inhalations that are left in the inhaler. Inhalers are available with either 14, 30 or 60 inhalations (doses), with each pack containing one pouched inhaler (for any of the 14, 30 or 60 dose inhalers) or three individually packed and pouched inhalers (only for the 60 dose inhalers). Not all pack sizes may be marketed.

Marketing Authorisation holder and manufacturer

Marketing Authorisation Holder:
Organon Pharma (Ireland) Limited
2 Dublin Landings
North Wall Quay - North Dock
Dublin, D01 V4A3
Ireland

Manufacturer:
Schering-Plough Labo N.V.
Industriepark 30, Zone A
B2220 Heist-op-den-Berg, Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Asmanex Twisthaler
Belgium: Asmanex Twisthaler 400 microgrammes Poudre pour inhalation
Denmark: Asmanex Twisthaler 400 mikrogram inhalationspulver
Finland: Asmanex Twisthaler
France: Asmanex Twisthaler 400 microgrammes/dose, poudre pour inhalation
Germany: Asmanex Twisthaler 400 Mikrogramm Pulver zur Inhalation
Greece: Asmanex Twisthaler
Iceland: Asmanex Twisthaler, 400 míkróg. Innöndunarduft
Ireland: Asmanex Twisthaler 400 micrograms Inhalation Powder
Italy: Asmanex 400 microgrammi polvere per inalazione
Norway: Asmanex Twisthaler
Portugal: Asmanex Twisthaler
Spain: Asmanex Twisthaler 400 microgramos polvo para inhalación
Sweden: Asmanex Twisthaler
United Kingdom: Asmanex Twisthaler 400 micrograms Inhalation Powder

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