



Package leaflet: Information for the user

Atimos® Modulite® 12 micrograms/actuation pressurised inhalation solution

Formoterol fumarate dihydrate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms 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 Atimos Modulite is and what it is used for
2. What you need to know before you use Atimos Modulite
3. How to use Atimos Modulite
4. Possible side effects
5. How to store Atimos Modulite
6. Contents of the pack and other information

1. What Atimos Modulite is and what it is used for?

Atimos Modulite is an inhalation medicine delivering its active ingredient directly into your lungs where it is needed. It is used to treat the symptoms of wheezing and breathlessness in patients with moderate to severe asthma. Its active ingredient, formoterol fumarate, belongs to a group of medicines called bronchodilators: they make breathing easier by relaxing muscle spasms in the air passages of the lungs. Regular use of Atimos Modulite together with steroids (either by inhaler or by mouth), will help to prevent breathing problems over the long term.

Atimos Modulite can also be used for the relief of symptoms such as cough, wheezing and shortness of breath in patients with chronic obstructive pulmonary disease (COPD) who require long-term regular bronchodilator therapy.

2. What you need to know before you use Atimos Modulite

Do not use Atimos Modulite:

- if you are allergic to formoterol or to any of the ingredients of this medicine Atimos Modulite (listed in section 6).
- to treat a sudden attack of breathlessness. It will not help. Use a reliever for this purpose and carry it with you at all times.

Warnings and precautions

Talk to your doctor or pharmacist before using Atimos Modulite if you:

- suffer from severe heart disease, especially a recent heart attack, a disease of the coronary vessels of the heart or severe weakness of the heart muscle (congestive heart failure)
- suffer from disorders of heart rhythm such as increased heart rate, heart valve defect or certain electrocardiogram abnormalities or any other heart disease
- have narrowing of the blood vessels, especially the arteries, or abnormal widening of the vessel wall
- suffer from high blood pressure
- have high sugar levels in the blood (diabetes mellitus)
- have low blood potassium levels
- have an overactive thyroid gland
- are suffering from epinephrine and nor-epinephrine producing tumours of the adrenal medulla.
- are going to have any surgery or receive halogenated anaesthetics

Other medicines and Atimos Modulite:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without prescription.

Some medicines may interfere with the action of Atimos Modulite, these include medicines:

- for treating abnormal heart rhythms (for example quinidine, disopyramide, procainamide)
- for treating heart disease (for example digitalis)
- for treating nasal congestion (for example ephedrine)
- called beta adrenergic blockers used to treat heart conditions or glaucoma (an increase of the pressure in the eye), as tablets or eye drops
- containing erythromycin (used to treat infections)
- for treating symptoms of depression: monoamine oxidase inhibitors (for example phenelzine and isocarboxazid) or tricyclic antidepressants (for example amitriptyline and imipramine)
- to treat severe mental disorders (for example chlorpromazine and trifluoperazine)
- used to treat allergic reactions (such as antihistamines, for example terfenadine, astemizole, mizolastine)
- used to treat bronchial asthma (for example theophylline, aminophylline or steroids)
- used to increase urine production (such as diuretics)
- for treating Parkinsonism (for example levodopa)
- containing oxytocin, which causes uterus contraction.
- to treat an underactive thyroid gland (for example thyroxine)

The addition of anticholinergics (such as tiotropium or ipratropium bromide) to the treatment with Atimos Modulite, can help to open your airways even more.

You have also been prescribed corticosteroids for your breathing problems. It is very important to keep using these regularly. **Do not stop** using them or change the dose when you start using Atimos Modulite.

Pregnancy and breast feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine Atimos Modulite.

The use of Atimos Modulite during pregnancy is only indicated if absolutely necessary.

Driving and using machines

Atimos Modulite is unlikely to have any effect on the ability to drive and operate machinery.

Atimos Modulite contains ethanol

This medicine contains a small amount of ethanol (alcohol): 8.9 mg of alcohol (ethanol) in each actuation, which is equivalent to 0.25 mg/kg per dose of two actuations in adults and equivalent to 0.44 mg/kg per dose of two actuations in adolescents. The amount in two actuations of this medicine is equivalent to less than 1 ml of wine or beer. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Atimos Modulite

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For Asthma

The dose of Atimos Modulite you must inhale will depend on the type of asthma you have and how severe it is. Your dose will be decided by your doctor and it is important that you only take the prescribed dose, regularly. The usual dose for adults, including the elderly and adolescents 12 years and older is 1 puff in the morning and 1 puff in the evening. This means you need to take a total of 2 puffs (24 micrograms) of Atimos Modulite per day.

If you suffer from more severe asthma your doctor may prescribe 4 puffs per day (48 micrograms), 2 puffs in the morning and 2 puffs in the evening.

4 puffs (48 micrograms) of Atimos Modulite is the maximum daily dose and it is important that you do not take more than the total daily dose that your doctor has told you to take.

This product is not suitable for asthmatic children under 12 years old.

For Chronic Obstructive Pulmonary Disease (COPD):

The usual dose for adults, including the elderly and adolescents 18 years and older is 1 puff in the morning and 1 puff in the evening. This means you need to take a total of 2 puffs (24 micrograms) of Atimos Modulite per day.

If you suffer from more severe COPD your doctor may prescribe 4 puffs per day (48 micrograms), 2 puffs in the morning and 2 puffs in the evening.

4 puffs (48 micrograms) of Atimos Modulite is the maximum daily dose and it is important that you do not take more than the total daily dose that your doctor has told you to take.

Do not take more than 2 puffs at any one time.

This product is not suitable for COPD patients under 18 years old.

Do not use Atimos Modulite to treat a sudden attack of breathlessness. You should use a "reliever" inhaler prescribed by your doctor for this purpose, carry this medicine with you at all times.

If you use more Atimos Modulite than you should:

You may notice that your heart is beating faster than usual and that you feel shaky. You may also have a headache, tremor, feeling and being sick (nausea and vomiting) or feel sleepy. Contact your doctor as soon as possible for advice.

If you forget to use Atimos Modulite:

If you forget to use Atimos Modulite, take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the usual time. **Do not double the dose.**

Do not stop or reduce the dose of Atimos Modulite or any other medicine for your breathing just because you feel better, without talking to your doctor first. It is very important to use these medicines regularly.

Do not increase your dose of Atimos Modulite without talking to your doctor first. If you feel you are getting breathless or wheezy while using Atimos Modulite, you should continue to use Atimos Modulite but go to see your doctor as soon as possible, you may need additional treatment. Once your asthma is well controlled, your doctor may consider it appropriate to gradually reduce the dose of Atimos Modulite.

Instructions for use

It is important that you know how to use your inhaler properly. Your doctor, nurse or pharmacist will show you how to use your inhaler correctly. You must follow their instructions carefully so that you know **how, when and how many** puffs to inhale. The correct instructions are given in this leaflet. If you are not sure what to do or have problems in inhaling then ask your doctor, nurse or pharmacist for advice.

Please read the back of this leaflet →

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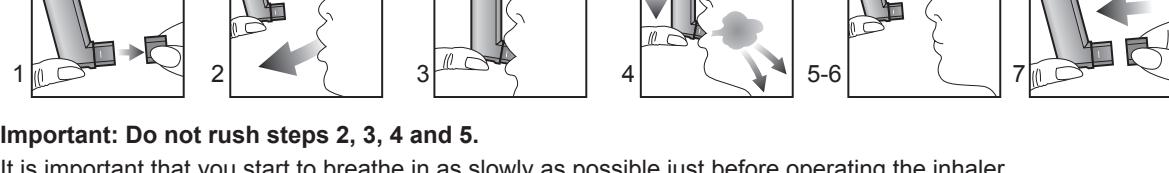
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Testing your inhaler. If your inhaler is new or if it has not been used for 3 days or more, one puff should be released into the air before using it, to make sure that it works.

You should stand or sit in the upright position when using your inhaler.

1. Remove the mouthpiece cover from the inhaler and hold it between the thumb and forefinger as shown.
2. Breathe out as far as is comfortable.
3. Hold the inhaler upright as shown with your thumb on the base below the mouthpiece; place the mouthpiece in your mouth between your teeth and close tightly your lips around it.
4. Breathe in deeply through your mouth and at the same time press down on the top of the inhaler to release a puff.
5. Hold your breath as long as is comfortable, then take the inhaler from your mouth.
6. If you are to take another puff, keep the inhaler upright and wait about half a minute before repeating steps 2 to 5.
7. After use always replace the mouthpiece cover to keep out dust and fluff. Replace firmly and snap into position.



Important: Do not rush steps 2, 3, 4 and 5.

It is important that you start to breathe in as slowly as possible just before operating the inhaler.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, Atimos Modulite will not get into your lungs as it should. Take another puff carefully following the instructions from Step 2 onwards.

If you have weak hands it may be easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece.

Tell your doctor, nurse or pharmacist if you have any difficulties.

Cleaning

It is important to clean your inhaler regularly, at least once or twice a week to ensure that it works properly.

- Pull the metal canister out of the plastic case of the inhaler and remove the mouthpiece cover.
- Rinse the plastic case and the mouthpiece cover in warm water.
- Do not put the metal canister into water.
- Leave to dry thoroughly in a warm place. Avoid excessive heat.
- Replace the canister and mouthpiece cover.

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 Atimos Modulite can cause side effects although not everybody gets them. Possible side effects are listed below according to their frequency. If you are not sure what the side effects below are, ask your doctor to explain them to you.

If your breathing or wheezing gets worse after using your inhaler stop using Atimos Modulite and tell your doctor immediately. This is caused by narrowing of the airways in your lungs but it occurs only rarely.

Common (may affect up to 1 in 10 people): unusually fast heart beat and palpitations, cough, trembling (fine tremor), headache.

Uncommon (may affect up to 1 in 100 people): muscles cramps, pain in muscles, nausea, agitation, restlessness, sleep disorders, dizziness, abnormal or impaired sense of taste, throat irritation, abnormal rapid heart beat, disorders of heart rhythm with increase heart rate, abnormal low levels of potassium in the blood, increase in blood sugar levels, increase in the blood level of insulin, free fatty acids, glycerol and ketones, excessive sweating.

Rare (may affect up to 1 in 1,000 people): missed heartbeats caused by too early contraction of the ventricles of the heart, feeling chest tightness, increase or decrease in blood pressure, wheezing immediately after using the inhaler, severe fall in blood pressure, inflammation of the kidneys, allergic reaction such as itching, rash, bronchospasm, urticaria, swelling of skin and mucous membrane persisting for several days.

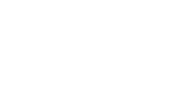
Very rare (may affect up to 1 in 10,000 people): worsening of asthma, difficulty breathing, swelling of the hands and/or feet, irregular heartbeat, reduced number of blood platelets, hyperexcitability, abnormal behaviour, hallucinations.

Some side effects, such as tremor, nausea, abnormal or impaired sense of taste, throat irritation, excessive sweating, restlessness, headache, dizziness and muscle cramps, may ease during the course of one to two weeks of continued use of your asthma medication.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist immediately. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.



5. How to store Atimos Modulite

- Keep this medicine out of the sight and reach of children.
- Do not use beyond three months from the date you get the inhaler from your pharmacist and never use after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.
- Do not store the inhaler above 30°C.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it **in your hands** for a few minutes before use. **Never** use anything else to warm it up.
- **Warning.** The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.
- Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Atimos Modulite contains:

The active substance of Atimos Modulite is formoterol fumarate dihydrate. Each metered actuation provides 12 micrograms of formoterol fumarate dihydrate. This corresponds to a delivered dose of 10.1 micrograms.

The other ingredients are: hydrochloric acid, ethanol and norflurane (HFC-134a).

This medicine contains fluorinated greenhouse gases.

Each inhaler of 50 actuations contains 5.842 g of norflurane (HFC-134a) corresponding to 0.08 tonne CO₂ equivalent (global warming potential GWP = 1430).

Each inhaler of 100 actuations contains 9.087 g of norflurane (HFC-134a) corresponding to 0.013 tonne CO₂ equivalent (global warming potential GWP = 1430).

Each inhaler of 120 actuations contains 10.384 g of norflurane (HFC-134a) corresponding to 0.015 tonne CO₂ equivalent (global warming potential GWP = 1430).

What Atimos Modulite looks like and contents of the pack:

Atimos Modulite is a pressurised inhalation solution contained in an aluminium can with plastic actuator and protective cap.

Each pack contains 1 inhaler which provides 50, 100 or 120 puffs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK.

Manufacturer responsible for batch release:

Chiesi Farmaceutici S.p.A., Via S. Leonardo 96, 43122 Parma, Italy

Alternative manufacturer responsible for batch release:

Chiesi Pharmaceuticals GmbH, Gonzagagasse 16/16, 1010 Wien, Austria

This medicinal product has been authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Czech Republic	ATIMOS
Germany	ATIFOR CHIESI
Portugal	ATIMOS
Estonia	ATIMOS
Spain	BRONCORAL NEO
Holland	ATIMOS
UK (Northern Ireland)	ATIMOS MODULITE

Slovak Republic	ATIMOS
Hungary	ATIMOS
Slovenia	ATIMOS
Poland	ATIMOS
Latvia	ATIMOS



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