

Package leaflet: Information for the user

Atecura[®] Breezhaler[®] 125 micrograms/62.5 micrograms inhalation powder, hard capsules
Atecura[®] Breezhaler[®] 125 micrograms/127.5 micrograms inhalation powder, hard capsules
Atecura[®] Breezhaler[®] 125 micrograms/260 micrograms inhalation powder, hard capsules
indacaterol/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, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Atecura Breezhaler is and what it is used for

What Atecura Breezhaler is and how it works

Atecura Breezhaler contains two active substances called indacaterol and mometasone furoate.

Indacaterol belongs to a group of medicines called bronchodilators. It relaxes the muscles of the small airways in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When it is taken regularly, it helps the small airways to remain open.

Mometasone furoate belongs to a group of medicines called corticosteroids (or steroids). Corticosteroids reduce the swelling and irritation (inflammation) in the small airways in the lungs and so gradually ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

What Atecura Breezhaler is used for

Atecura Breezhaler is used regularly as treatment for asthma in adults and adolescents (12 years of age and older).

Asthma is a serious, long-term lung disease where the muscles surrounding the smaller airways become tight (bronchoconstriction) and inflamed. Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

You should use Atecura Breezhaler every day and not only when you have breathing problems or other symptoms of asthma. This will ensure that it controls your asthma properly. Do not use this medicine to relieve a sudden attack of breathlessness or wheezing.

If you have any questions about how Atecura Breezhaler works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you use Ateectura Breezhaler

Follow all the doctor's instructions carefully.

Do not use Ateectura Breezhaler

- if you are allergic to indacaterol, mometasone furoate or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor, pharmacist or nurse **before** using Ateectura Breezhaler if any of the following applies to you:

- if you have heart problems, including an irregular or fast heartbeat.
- if you have thyroid gland problems.
- if you have ever been told you have diabetes or high blood sugar.
- if you suffer from seizures or fits.
- if you have a low level of potassium in your blood.
- if you have severe liver problems.
- if you have tuberculosis (TB) of the lung, or any long-standing or untreated infections.

During treatment with Ateectura Breezhaler

Stop using this medicine and get medical help immediately if you have any of the following:

- tightness of the chest, coughing, wheezing or breathlessness immediately after using Ateectura Breezhaler (signs the medicine is unexpectedly tightening the airways, known as paradoxical bronchospasm).
- difficulty breathing or swallowing, swelling of the tongue, lips or face, skin rash, itching and hives (signs of allergic reaction).

Children and adolescents

Do not give this medicine to children below 12 years of age because it has not been studied in this age group.

Other medicines and Ateectura Breezhaler

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, tell your doctor or pharmacist if you are using:

- medicines that decrease the level of potassium in your blood. These include diuretics (which increase urine production and can be used to treat high blood pressure, e.g. hydrochlorothiazide), other bronchodilators such as methylxanthines used for breathing problems (e.g. theophylline) or corticosteroids (e.g. prednisolone).
- tricyclic antidepressants or monoamine oxidase inhibitors (medicines used in the treatment of depression).
- any medicines that may be similar to Ateectura Breezhaler (contain similar active substances); using them together may increase the risk of possible side effects.
- medicines called beta blockers used to treat high blood pressure or other heart problems (e.g. propranolol) or to treat glaucoma (e.g. timolol).
- ketoconazole or itraconazole (medicines used to treat fungal infections)
- ritonavir, nelfinavir or cobicistat (medicines used to treat HIV infection).

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 for advice before taking this medicine. Your doctor will discuss with you whether you can use Ateectura Breezhaler.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive and use machines.

Ateectura Breezhaler contains lactose

This medicine contains about 25 mg of lactose per capsule. If you have been told by your doctor that

you have an intolerance to some sugars, speak with your doctor before taking this medicine.

3. How to use Ateectura Breezhaler

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

How much Ateectura Breezhaler to inhale

There are three different strengths of Ateectura Breezhaler capsules. Your doctor will decide which is best for you.

The usual dose is to inhale the content of one capsule each day. You only need to use the medicine once a day. Do not use more than your doctor tells you to use.

You should use Ateectura Breezhaler every day, even when your asthma is not troubling you.

When to inhale Ateectura Breezhaler

Inhale Ateectura Breezhaler at the same time each day. This will help control your symptoms throughout the day and night. It will also help you to remember to use it.

How to inhale Ateectura Breezhaler

- Ateectura Breezhaler is for inhalation use.
- In this pack, you will find an inhaler and capsules that contain the medicine. The inhaler enables you to inhale the medicine in the capsule. Only use the capsules with the inhaler provided in this pack. The capsules should remain in the blister until you need to use them.
- Peel the backing away from the blister to open it, **do not push the capsule through the foil.**
- When you start a new pack, use the new inhaler supplied in this new pack.
- Dispose of the inhaler in each pack after all capsules in that pack have been used.
- Do not swallow the capsules.
- **Please read the instructions for use on the other side of this leaflet for more information on how to use the inhaler.**

If your symptoms do not improve

If your asthma is not getting better or if it gets worse after you have started using Ateectura Breezhaler, talk to your doctor.

If you use more Ateectura Breezhaler than you should

If you accidentally inhale too much of this medicine, contact your doctor or hospital for advice immediately. You may need medical attention.

If you forget to use Ateectura Breezhaler

If you forget to inhale a dose at the usual time, inhale one as soon as possible on that day. Then inhale the next dose at the usual time on the next day. Do not inhale two doses on the same day.

If you stop using Ateectura Breezhaler

Do not stop using Ateectura Breezhaler unless your doctor tells you to. Your asthma symptoms may come back if you stop using it.

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.

Some side effects could be serious

Stop using Ateectura Breezhaler and get medical help immediately if you have any of the following:

Common: may affect up to 1 in every 10 people

- difficulty breathing or swallowing, swelling of the tongue, lips, or face, skin rash, itching and hives (signs of allergic reaction).

Uncommon: may affect up to 1 in every 100 people

- swelling mainly of the tongue, lips, face or throat (possible signs of angioedema).

Other side effects

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or nurse.

Very common: may affect more than 1 in 10 people

- sore throat
- runny nose
- sudden difficulty breathing and feeling of tightness in chest with wheezing or coughing

Common: may affect up to 1 in every 10 people

- voice alteration (hoarseness)
- blocked nose
- sneezing, cough
- headache
- pain in muscles, bones or joints (signs of musculoskeletal pain)

Uncommon: may affect up to 1 in every 100 people

- fast heart beat
- oral thrush (sign of candidiasis)
- high level of sugar in the blood
- muscle spasm
- skin itching
- rash
- clouding of the lens of your eyes (signs of cataract)
- blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Ateectura Breezhaler

- 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 and blister after "EXP". The expiry date refers to the last day of that month.
- This medicinal product does not require any special temperature storage conditions.
- Store the capsules in the original blister in order to protect from light and moisture, and do not remove until immediately before use.
- Do not throw away any medicines via wastewater. 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 Ateectura Breezhaler contains

- The active substances are indacaterol (as acetate) and mometasone furoate.

Ateectura Breezhaler 125 micrograms/62.5 micrograms

Each capsule contains 173 micrograms of indacaterol acetate (equivalent to 150 micrograms of indacaterol) and 80 micrograms of mometasone furoate. The delivered dose (the dose that leaves the mouthpiece of the inhaler) is equivalent to 125 micrograms of indacaterol and 62.5 micrograms of mometasone furoate.

Ateectura Breezhaler 125 micrograms/127.5 micrograms

Each capsule contains 173 micrograms of indacaterol acetate (equivalent to 150 micrograms of indacaterol) and 160 micrograms of mometasone furoate. The delivered dose (the dose that leaves the mouthpiece of the inhaler) is equivalent to 125 micrograms of indacaterol and 127.5 micrograms of mometasone furoate.

Ateectura Breezhaler 125 micrograms/260 micrograms

Each capsule contains 173 micrograms of indacaterol acetate (equivalent to 150 micrograms of indacaterol) and 320 micrograms of mometasone furoate. The delivered dose (the dose that leaves the mouthpiece of the inhaler) is equivalent to 125 micrograms of indacaterol and 260 micrograms of mometasone furoate.

- The other ingredient is lactose monohydrate (see “Ateectura Breezhaler contains lactose” in section 2).

What Ateectura Breezhaler looks like and content of the pack

In this pack, you will find an inhaler together with capsules in blisters. The capsules are transparent and contain a white powder.

- Ateectura Breezhaler 125 micrograms/62.5 micrograms capsules have a blue product code “IM150-80” printed above one blue bar on the body with a logo printed in blue and surrounded by two blue bars on the cap.
- Ateectura Breezhaler 125 micrograms/127.5 micrograms capsules have a grey product code “IM150-160” printed on the body with a logo printed in grey on the cap.
- Ateectura Breezhaler 125 micrograms/260 micrograms capsules have a black product code “IM150-320” printed above two black bars on the body with a logo printed in black and surrounded by two black bars on the cap.

The following pack sizes are available:

Single pack containing 10 x 1 or 30 x 1 hard capsules, together with 1 inhaler.

Multipacks comprising 3 cartons, each containing 30 x 1 hard capsules together with 1 inhaler.

Multipacks comprising 15 cartons, each containing 10 x 1 hard capsules together with 1 inhaler.

Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Novartis Europharm Limited

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Ireland

Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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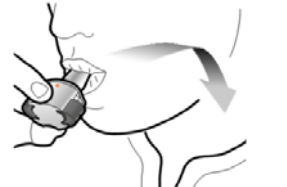
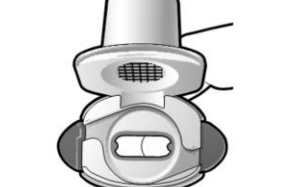
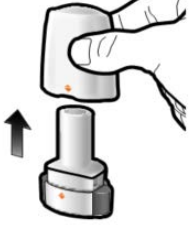

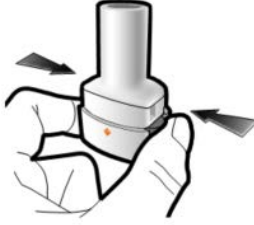





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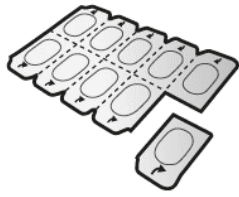
Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

Instructions for Use of Atectura Breezhaler

Please read full instructions for use of Atectura Breezhaler inhaler before use. These instructions are also available by scanning the QR code or visiting www.breezhaler-asthma.eu/atectura

“QR code to be included”.

			
Insert 1	Pierce and release 2	Inhale deeply 3	Check capsule is empty Check
 <p>Step 1a: Pull off cap</p>  <p>Step 1b: Open inhaler</p>	 <p>Step 2a: Pierce capsule once Hold the inhaler upright. Pierce capsule by firmly pressing both side buttons at the same time.</p> <p>You should hear a noise as the capsule is pierced. <u>Only pierce the capsule once.</u></p>  <p>Step 2b: Release side buttons</p>	<p>Step 3a: Breathe out fully <u>Do not blow into the inhaler.</u></p>  <p>Step 3b: Inhale medicine deeply Hold the inhaler as shown in the picture. Place the mouthpiece in your mouth and close your lips firmly around it. <u>Do not press the side buttons.</u></p>	 <p>Check capsule is empty Open the inhaler to see if any powder is left in the capsule.</p> <p>If there is powder left in the capsule:</p> <ul style="list-style-type: none"> • Close the inhaler. • Repeat steps 3a to 3d.  <p>Powder remaining</p>  <p>Empty</p>



Step 1c:

Remove capsule

Separate one of the blisters from the blister card.

Peel open the blister and remove the capsule.

Do not push the capsule through the foil.

Do not swallow the capsule.

Breathe in quickly and as deeply as you can. During inhalation you will hear a whirring noise. You may taste the medicine as you inhale.



Step 3c:

Hold breath

Hold your breath for up to 5 seconds.

Step 3d:

Rinse mouth

Rinse your mouth with water after each dose and spit it out.



Remove empty capsule

Put the empty capsule in your household waste. Close the inhaler and replace the cap.



Step 1d:

Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:

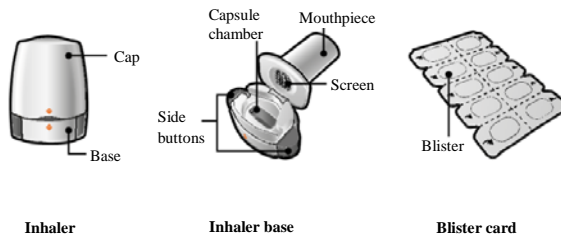
Close inhaler

Important Information

- Aectura Breezhaler capsules must always be stored in the blister card and only removed immediately before use.
- Do not push the capsule through the foil to remove it from the blister.
- Do not swallow the capsule.
- Do not use the Aectura Breezhaler capsules with any other inhaler.
- Do not use the Aectura Breezhaler inhaler to take any other capsule medicine.
- Never place the capsule into your mouth or the mouthpiece of the inhaler.
- Do not press the side buttons more than once.
- Do not blow into the mouthpiece.
- Do not press the side buttons while inhaling through the mouthpiece.
- Do not handle capsules with wet hands.
- Never wash your inhaler with water.

Your Atectura Breezhaler Inhaler pack contains:

- One Atectura Breezhaler inhaler
- One or more blister cards, each containing 10 Atectura Breezhaler capsules to be used in the inhaler



Inhaler

Inhaler base

Blister card

Frequently Asked Questions

Why didn't the inhaler make a noise when I inhaled?

The capsule may be stuck in the capsule chamber. If this happens, carefully loosen the capsule by tapping the base of the inhaler. Inhale the medicine again by repeating steps 3a to 3d.

What should I do if there is powder left inside the capsule?

You have not received enough of your medicine. Close the inhaler and repeat steps 3a to 3d.

I coughed after inhaling – does this matter?

This may happen. As long as the capsule is empty you have received enough of your medicine.

I felt small pieces of the capsule on my tongue – does this matter?

This can happen. It is not harmful. The chances of the capsule breaking into small pieces will be increased if the capsule is pierced more than once.

Cleaning the inhaler

Wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry. Never wash your inhaler with water.

Disposing of the inhaler after use

Each inhaler should be disposed of after all capsules have been used. Ask your pharmacist how to dispose of medicines and inhalers that are no longer required.