

Bretaris® Genuair®

inhalation powder

acclidinium bromide

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Bretaris Genuair.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your pharmacist or doctor will be able to advise you about the risks and benefits of using Bretaris Genuair.

If you have any concerns about using this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT BRETARIS GENUAIR IS USED FOR

The active ingredient of Bretaris Genuair is acclidinium bromide, which belongs to a group of medicines called bronchodilators. Bronchodilators relax airways and help keep bronchioles open. Bretaris Genuair is a dry powder inhaler that uses your breath to deliver the medicine directly into your lungs. This makes it easier for chronic obstructive pulmonary disease (COPD) patients to breathe.

Bretaris Genuair is indicated to help open the airways and relieve symptoms of COPD, a serious, long-term lung disease characterised by breathing difficulties. Regular use of Bretaris Genuair can help you when you have ongoing shortness of breath related to your disease and will help you to minimise the effects of the disease on your everyday life.

Ask your doctor if you have any questions about why Bretaris Genuair has been prescribed for you.

This medicine is only available with a doctor's prescription.

It is not addictive.

BEFORE YOU USE BRETARIS GENUAIR

When you must not use it

Do not use Bretaris Genuair

- if you are allergic to acclidinium bromide or any of the other ingredients of this medicine listed at the end of this leaflet
- if you are allergic to atropine or related bronchodilator medicines for example ipratropium, tiotropium or oxitropium.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to use it

Tell your doctor if you have any of the following medical conditions:

- if you have asthma if you have had heart problems recently
- if you see halos around lights or coloured images (glaucoma)
- if you have an enlarged prostate, problems passing urine, or a blockage in your bladder.

Your doctor may want to take special precautions if you have any of the above conditions.

Bretaris Genuair is indicated for maintenance treatment of your chronic obstructive pulmonary disease; it should not be used to treat a sudden attack of breathlessness or wheezing. If your COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse you should contact your doctor for advice as soon as possible.

Dry mouth, which has been observed with medicines like Bretaris Genuair, may, after using your medicine for a long time, be associated with tooth decay. Therefore, please remember to pay attention to oral hygiene.

Stop taking Bretaris Genuair and seek medical help immediately:

- if you get tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine. These may be signs of a condition called bronchospasm.

If you require further advice, you should talk with your doctor or pharmacist.

Tell your doctor if you are pregnant, intend to become pregnant or are breastfeeding.

Bretaris Genuair is not recommended for use during pregnancy or while breastfeeding. If it is necessary for you to use this medicine during pregnancy or while breastfeeding, your doctor will discuss with you the benefits and risks involved.

Children and adolescents

Bretaris Genuair is not for use in children or adolescents below 18 years of age.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Bretaris Genuair may interfere with each other. These include medicines containing

- **tiotropium,**
- **ipratropium or oxitropium (called anticholinergics).**

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start using Bretaris Genuair.

HOW TO USE BRETARIS GENUAIR

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the end of this leaflet, ask your doctor or pharmacist for help.

How much to use

The recommended dose is one inhalation twice a day in the morning and evening.

The effects of Bretaris Genuair last for 12 hours; therefore, you should try to use your Bretaris Genuair inhaler at the same time every morning and evening. This ensures that there is always enough medicine in your body to help you breathe more easily throughout the day and night. It will also help you to remember to use it.

How to use

See instructions on how to use the Genuair inhaler at the end of this leaflet. If you are not sure of how to use Bretaris Genuair, contact your doctor or pharmacist.

How long to use

Continue to use this medicine for as long as your doctor tells you to.

If it helps your breathing problems, your doctor may want you to keep using it for a long time. This medicine helps to control your condition but it does not cure it.

If you want to stop treatment, first talk to your doctor, as your symptoms may worsen.

If you forget to use Bretaris Genuair

If you forget a dose of Bretaris Genuair, inhale the dose as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

WHILE YOU ARE USING BRETARIS GENUAIR

Things you must do

Use this medicine exactly as your doctor has prescribed. Try not to miss any doses and use it even if you feel well.

If you do not follow your doctor's instructions, you may not get relief from your breathing problems or you may have unwanted side effects.

If you find that the usual dose of Bretaris Genuair is not giving as much relief as before, or does not last as long as usual, contact your doctor so that your condition can be checked.

This is important to ensure your COPD is controlled properly.

If you become pregnant while using this medicine, tell your doctor.

Your doctor can discuss with you the risks of using it while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Bretaris Genuair.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Things you must not do

Do not exceed the recommended daily dose - it will not help you to do this.

Do not take any other medicines for your breathing problems without checking with your doctor.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Bretaris affects you.

This medicine has no or negligible influence on the ability to drive and use machines. This medicine may cause headache or blurred vision. If you are affected by either of these side effects do not drive or use machinery until the headache has cleared and your vision has returned to normal.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Bretaris Genuair.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Headache
- Inflammation of the sinuses (sinusitis)

- Sneezing (rhinitis)
- Common cold (nasopharyngitis)
- Cough
- Diarrhoea
- Vomiting
- Toothache
- Fall

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- you develop signs of an allergic reaction such as swelling of the face, lips, tongue, throat or other part of the body; severe dizziness or fainting; redness, itching or rash on the skin.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

IF YOU USE TOO MUCH (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Bretaris. Do this even if there are no signs of discomfort or poisoning.

AFTER USING BRETARIS GENUAIR

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep the Genuair inhaler protected inside the sealed pouch until the administration period starts.

To be used within 90 days of opening the pouch.

Store below 30°C.

Disposal

If your pharmacist or doctor tells you to stop using the inhaler or the expiry date has passed, ask your pharmacist how to dispose of it properly.

PRODUCT DESCRIPTION

What it looks like

Bretaris Genuair is a white or almost white powder.

The Genuair inhaler device is white coloured with an integral dose indicator and a green dosage button. The mouthpiece is covered with a removable green protective cap. It is supplied in a sealed protective pouch.

Ingredients

Active Ingredient

The active substance is acclidinium bromide. Each delivered dose contains 375 micrograms acclidinium bromide equivalent to 322 micrograms of acclidinium.

Inactive Ingredient

Bretaris Genuair also contains lactose.

Sponsor

Bretaris Genuair is supplied in Australia by:

A. Menarini Australia Pty Ltd
Level 8, 67 Albert Avenue,
Chatswood, NSW 2067
Australia

This leaflet was prepared in March 2014

Australian Register Number(s)
322 microgram inhalation powder:
AUST R 206071

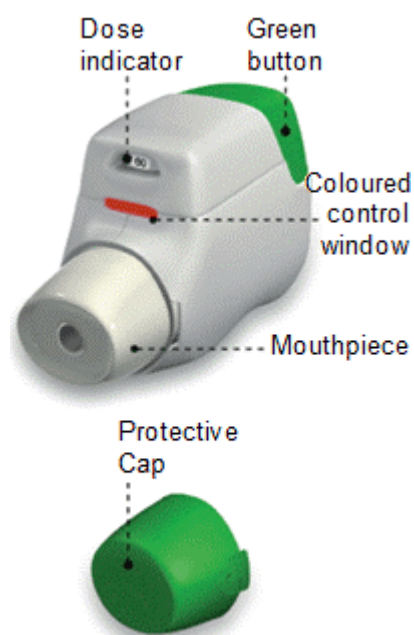
The Genuair inhaler: instructions for use

This section contains information on how to use your Genuair inhaler. If you have any questions about how to use your inhaler, please ask your doctor, pharmacist or nurse for assistance.

Before using the Genuair inhaler, please read the full instructions.

Becoming familiar with Bretaris Genuair:

Remove the Genuair inhaler from the pouch and become familiar with its components.



How to Use Bretaris Genuair

Summary

To use your Genuair inhaler there are 2 steps you need to perform after removing the cap:

- **Step 1:** Press and **RELEASE** the green button and breathe out completely, away from the inhaler.
- **Step 2:** Place your lips tightly around the mouthpiece and inhale **STRONGLY** and **DEEPLY** through the inhaler.

After inhalation, remember to replace the protective cap.

Getting Started

- Before first use, tear the sealed pouch along the notch and remove the Genuair inhaler.
- When you are about to take your dose of medicine, remove the protective cap by **lightly squeezing the arrows** marked on each side and pulling outwards (see image 1).

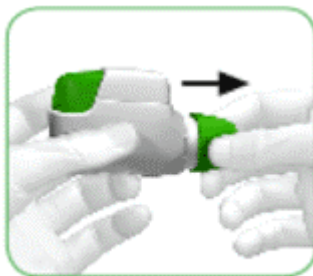


IMAGE 1

- Look to see that nothing is blocking the mouthpiece.
- Hold the Genuair inhaler **horizontally** with the mouthpiece towards you and the green button facing **straight up** (see image 2).

Hold with the green button facing straight up. DO NOT TILT.



IMAGE 2

STEP 1: PRESS all the way down and then RELEASE the green button and breathe out completely, away from the inhaler.

- Before bringing the inhaler to your mouth, press the green button all the way down (see image 3), then **RELEASE** it (see image 4).

DO NOT CONTINUE TO HOLD THE GREEN BUTTON DOWN.

PRESS the green button all the way down



IMAGE 3

RELEASE the green button



IMAGE 4

Stop and Check: Make sure the dose is ready for inhalation

- Make sure the coloured control window has changed to **green** (see image 5).

Ready to use



IMAGE 5

- The green control window confirms that your medicine is ready for inhalation.

IF THE COLOURED CONTROL WINDOW STAYS RED, PLEASE REPEAT PRESS AND RELEASE ACTIONS (SEE STEP 1).

- Before bringing the inhaler to your mouth, breathe out completely. Do not breathe out into the inhaler.

STEP 2: Inhale STRONGLY and DEEPLY through the mouthpiece.

- Put your lips tightly around the mouthpiece of the Genuair inhaler and breathe in **STRONGLY** and **DEEPLY** through your mouth (see image 6).
- This strong, deep breath pulls the medicine through the inhaler into your lungs.

ATTENTION: DO NOT HOLD THE GREEN BUTTON DOWN WHILE YOU ARE INHALING.

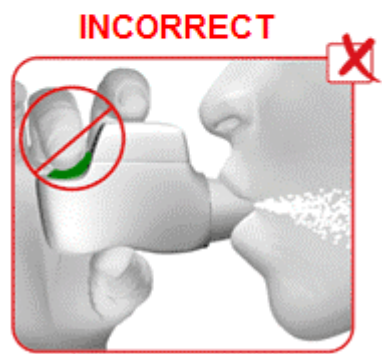
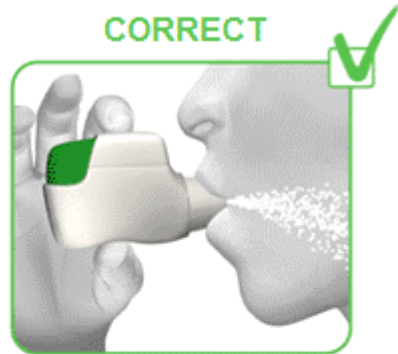


IMAGE 6

- While you breathe in you will hear a "CLICK" which signals that you are using the Genuair inhaler correctly.
- Keep breathing in even after you have heard the inhaler "CLICK" to be sure you get the full dose.
- Remove the Genuair inhaler from your mouth and hold your breath for as long as is comfortable, then breathe out slowly through your nose.

Note: Some patients may experience a mild sweet or slightly bitter taste, depending on the patient, when inhaling the medicine. Do not take an extra dose if you do not taste anything after inhaling.

Stop and Check: Make sure you have inhaled correctly

- Make sure the control window has turned to **red** (see image 7). This confirms that you have inhaled your full dose correctly.

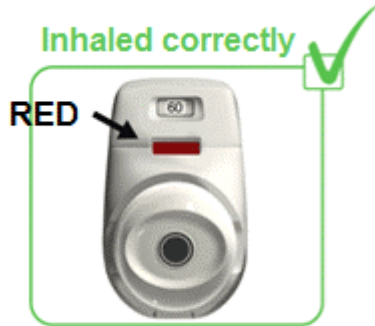


IMAGE 7

IF THE COLOURED CONTROL WINDOW IS STILL GREEN, PLEASE REPEAT INHALING STRONGLY AND DEEPLY THROUGH THE MOUTHPIECE (SEE STEP 2).

- If the window still does not change to red, you may have forgotten to release the green button before inhaling or may not have inhaled correctly. If that happens, try again.

Make sure you have RELEASED the green button and take a STRONG deep breath in through the mouthpiece.

Note: If you are unable to inhale correctly after several attempts, consult your doctor.

- Once the window has turned red, replace the protective cap by pressing it back onto the mouthpiece (see image 8).

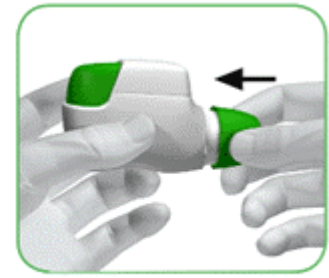


IMAGE 8

When should you get a new Genuair inhaler?

- The Genuair inhaler is equipped with a **dose indicator** to show you approximately how many doses are left in the inhaler. The dose indicator moves down slowly, displaying **intervals of 10** (60, 50, 40, 30, 20, 10, 0) (see image A). Every Genuair inhaler will deliver at least 30 doses.

When a **red striped band** appears in the dose indicator (see image A), this means you are nearing your last dose and you should obtain a new Genuair inhaler.

Dose indicator goes down by intervals of 10: 60, 50, 40, 30, 20, 10, 0.

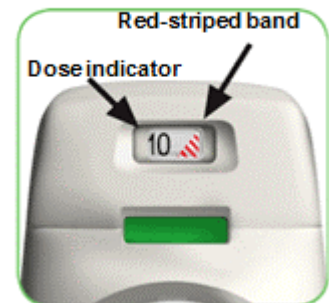


IMAGE A

Note: If your Genuair inhaler appears to be damaged or if you lose the cap, your inhaler should be replaced. You **DO NOT NEED** to clean your Genuair inhaler. However, if you wish to clean it you should do so by wiping the outside of the mouthpiece with a dry tissue or paper towel.

NEVER use water to clean the Genuair inhaler, as this may damage your medicine.

How do you know that your Genuair inhaler is empty?

- When 0 (zero) appears in the middle of the dose indicator, you should continue using any doses remaining in the Genuair inhaler.
- When the last dose has been prepared for inhalation, the green button will not return to its full upper position, but will be locked in a middle position (see image B). Even though the green button is locked, your last dose may still be inhaled. After that, the Genuair inhaler cannot be used again and you should start using a new Genuair inhaler.



IMAGE B