

BRIMICA® GENUAIR 340/12® Powder for inhalation

acilidium (as bromide)/efomoterol fumarate dihydrate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about BRIMICA GENUAIR 340/12.

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 BRIMICA GENUAIR 340/12.

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

Keep this leaflet with the medicine.

You may need to read it again.

What BRIMICA GENUAIR 340/12 is used for

BRIMICA GENUAIR 340/12 contains two different medicines called acilidium bromide and efomoterol fumarate dihydrate.

Both belong to a group of medicines known as bronchodilators. Bronchodilators relax airways and help keep bronchioles open. BRIMICA GENUAIR 340/12 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.

BRIMICA GENUAIR 340/12 is used to help open the airways and relieve symptoms of COPD, a serious long-term lung disease characterised by breathing difficulties. Regular use of BRIMICA GENUAIR 340/12 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 BRIMICA GENUAIR 340/12 has been prescribed for you.

This medicine is only available with a doctor's prescription. It is not addictive.

Before you use BRIMICA GENUAIR 340/12

When you must not use it

Do not use BRIMICA GENUAIR 340/12 if you are allergic to acilidium bromide, efomoterol fumarate dihydrate or to the other ingredient of this medicine listed at the end of this leaflet.

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 or pharmacist if you have any of the following medical conditions:

- if you have asthma
- if you have had heart problems recently
- if you have epilepsy
- if you have thyroid gland problems (thyrotoxicosis)
- if you have a tumour in one of your adrenal glands (phaeochromocytoma)
- if you have difficulty passing urine
- if you have an eye problem called narrow angle glaucoma.

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

BRIMICA GENUAIR 340/12 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.

If you see halos around lights and coloured images, have eye pain or discomfort or suffer temporary blurring of vision, see your doctor for advice as soon as possible.

Dry mouth, which has been observed with medicines like BRIMICA GENUAIR 340/12, 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 BRIMICA GENUAIR 340/12 and seek medical help immediately:

- if you have sudden difficulty in breathing or swallowing, if you have swelling of the tongue, throat, lips or face, or a skin rash and/or itching. These may be signs of an allergic reaction.
- 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 or pharmacist if you are pregnant or intend to become pregnant or are breastfeeding.

BRIMICA GENUAIR 340/12 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

BRIMICA GENUAIR 340/12 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 BRIMICA GENUAIR 340/12 may interfere with each other. These include:

- Any medicines that may be similar to BRIMICA GENUAIR 340/12 to treat breathing difficulties

- Medicines that lower the amount of potassium in your blood. These include:

- Steroids that you take by mouth (prednisolone)
- Diuretics (such as furosemide or hydrochlorothiazide)
- Certain medicines used to treat breathing conditions (such as theophylline).
- Medicines called beta blockers that may be used to treat high blood pressure or other heart problems (such as atenolol or propranolol) or to treat glaucoma (such as timolol)
- Medicines which can cause a change in your heart trace (electrocardiogram) known as QT interval prolongation. These include medicines for the treatment of:
 - Depression, such as monoamine oxidase inhibitors or tricyclic antidepressants.
 - Bacterial infections (such as erythromycin, clarithromycin, telithromycin).
 - Allergic reaction (anti-histamines).

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 BRIMICA GENUAIR 340/12.

How to use BRIMICA GENUAIR 340/12

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions at 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 at night, 12 hours apart.

The effects of BRIMICA GENUAIR 340/12 last for 12 hours; therefore, you should try to use your BRIMICA GENUAIR 340/12 inhaler in the morning and at night and should be taken 12 hours apart. 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 BRIMICA GENUAIR 340/12 inhaler at the end of this leaflet. If you are not sure of how to use BRIMICA GENUAIR 340/12, contact your doctor or pharmacist.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

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 take it

If you forget to have a dose of BRIMICA GENUAIR 340/12, 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 BRIMICA GENUAIR 340/12

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 BRIMICA GENUAIR 340/12 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 BRIMICA GENUAIR 340/12.

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 BRIMICA GENUAIR 340/12 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 BRIMICA GENUAIR 340/12.

All medicines may have some unwanted side effects. Sometimes they are serious but 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:

- Headaches
- Inflammation of the sinuses (sinusitis)
- Common cold (nasopharyngitis)
- Diarrhoea
- Vomiting
- Toothache
- Dry mouth
- Nausea
- Changes in voice
- Flu symptoms
- Changes in sense of taste
- Sore mouth or throat from inhaling the powder
- Being unable to sleep
- Dizziness
- Palpitation (feeling that your heartbeat is unusually fast or irregular)
- Muscle aching or cramp
- Trembling or shakiness
- Painful and/or frequent urination-these may be signs of a urinary tract infection
- Infection in the tissues at the base of a tooth
- Irritation in the throat
- Difficulty in breathing
- Blurred vision
- Swelling of hands, ankles or feet

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

- you develop signs of an allergic reaction such as swelling of the face, lips, tongue, throat or other part of the body; difficulty in breathing, palpitations, 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 take 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 BRIMICA GENUAIR 340/12. Do this even if there are no signs of discomfort or poisoning.

After using BRIMICA GENUAIR 340/12

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 BRIMICA GENUAIR 340/12 inhaler protected inside the sealed pouch until the administration period starts.

To be used within 60 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

BRIMICA GENUAIR 340/12 is a white or almost white powder.

The BRIMICA GENUAIR 340/12 inhaler device is white coloured with an integral dose indicator and an orange dosage button. The mouthpiece is covered with an orange removable protective cap. It is supplied in a sealed pouch.

Ingredients

Active ingredients:

Each delivered dose contains:
396 micrograms acilidium bromide (equivalent to 340 micrograms acilidium) /12 micrograms of efomoterol fumarate dihydrate

Inactive ingredients:

BRIMICA GENUAIR 340/12 also contains lactose.

Sponsor

BRIMICA GENUAIR 340/12 is supplied in Australia by:

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

1800 644 542

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For the most up to date version of this document please go to

www.menarinipac.com.au/cmi

Australian Registration Number(s)

AUST R 224899

Version No. 1

The BRIMICA® GENUAIR inhaler

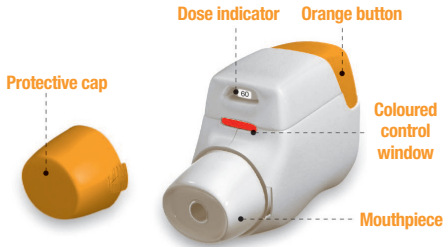
Instructions for use

This section contains information on how to use your BRIMICA GENUAIR 340/12 inhaler. If you have any questions about how to use your inhaler, please ask your doctor, pharmacist or nurse for assistance.

Before using the BRIMICA GENUAIR 340/12 inhaler, please read the full instructions.

Becoming familiar with BRIMICA GENUAIR 340/12:

Remove the BRIMICA GENUAIR 340/12 inhaler from the pouch and become familiar with its components.



How to Use BRIMICA GENUAIR 340/12

Summary

To use your BRIMICA GENUAIR 340/12 inhaler there are 2 steps you need to perform after removing the cap:

Step 1: **PRESS** and **RELEASE** the orange 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 BRIMICA GENUAIR 340/12 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).

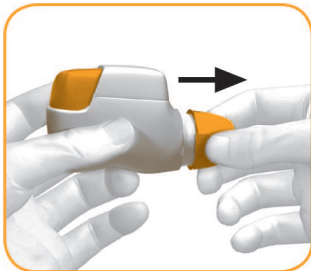


IMAGE 1

- Look to see that nothing is blocking the mouthpiece.
- Hold the BRIMICA GENUAIR 340/12 inhaler **horizontally** with the mouthpiece towards you and the orange button facing **straight up** (see image 2).

Hold with the orange button facing straight up. **DO NOT TILT.**



IMAGE 2

STEP 1: PRESS and RELEASE.

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

DO NOT CONTINUE TO HOLD THE ORANGE BUTTON DOWN.

PRESS the orange button all the way down



IMAGE 3

RELEASE the orange button



IMAGE 4

Stop and Check: Make sure dose is ready for inhalation

- Make sure the coloured control window has changed to **green** (see image 5).
- The green control window confirms that your medicine is ready for inhalation.



IMAGE 5

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.

- 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 orange button down while you are inhaling.

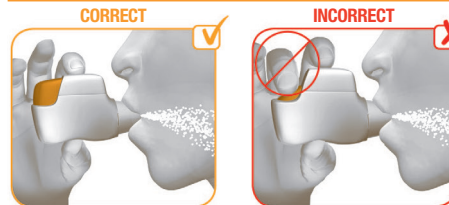


IMAGE 6

- While you breathe in you will hear a "CLICK" which signals that you are using the BRIMICA GENUAIR 340/12 inhaler correctly.
- Keep breathing in even after you have heard the inhaler "CLICK" to be sure you get the full dose.
- Remove the BRIMICA GENUAIR 340/12 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 taste 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 orange button before inhaling or may not have inhaled correctly. If that happens, try again.

Make sure you have RELEASED the orange 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).

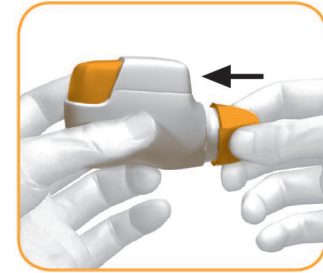


IMAGE 8

When should you get a new BRIMICA GENUAIR 340/12 inhaler?

- The BRIMICA GENUAIR 340/12 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** (e.g. 60, 50, 40, 30, 20, 10, 0) (see image A). Every BRIMICA GENUAIR 340/12 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 BRIMICA GENUAIR 340/12 inhaler.

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

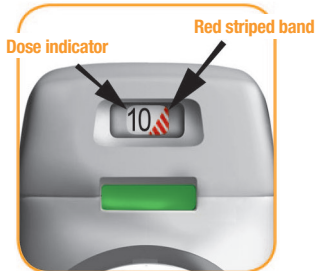


IMAGE A

Note: If your BRIMICA GENUAIR 340/12 inhaler appears to be damaged or if you lose the cap, your inhaler should be replaced. You **DO NOT** NEED to clean your BRIMICA GENUAIR 340/12 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 BRIMICA GENUAIR 340/12 inhaler, as this may damage your medicine.

How do you know that your BRIMICA GENUAIR 340/12 inhaler is empty?

- When 0 (zero) appears in the middle of the dose indicator, you should continue using any doses remaining in the BRIMICA GENUAIR 340/12 inhaler.
- When the last dose has been prepared for inhalation, the orange button will not return to its full upper position, but will be locked in a middle position (see image B). Even though the orange button is locked, your last dose may still be inhaled. After that, the BRIMICA GENUAIR 340/12 inhaler cannot be used again and you should start using a new BRIMICA GENUAIR 340/12 inhaler.



IMAGE B