

BRIMICA® GENUAIR® 340/12

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BRIMICA GENUAIR 340/12?

BRIMICA GENUAIR 340/12 contains the active ingredient acclidinium bromide and formoterol fumarate dihydrate. BRIMICA GENUAIR 340/12 is used to open the airways and make breathing easier to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD) as a long-term maintenance bronchodilator treatment.

For more information, see Section [1. Why am I using BRIMICA GENUAIR 340/12?](#) in the full CMI.

2. What should I know before I use BRIMICA GENUAIR 340/12?

Do not use if you have ever had an allergic reaction to BRIMICA GENUAIR 340/12 or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use BRIMICA GENUAIR 340/12?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BRIMICA GENUAIR 340/12 and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use BRIMICA GENUAIR 340/12?

- The recommended dose is one inhalation of BRIMICA GENUAIR 340/12 twice a day in the morning and night, 12 hours apart.

More instructions can be found in Section [4. How do I use BRIMICA GENUAIR 340/12?](#) in the full CMI.

5. What should I know while using BRIMICA GENUAIR 340/12?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using BRIMICA GENUAIR 340/12. - Use this medicine exactly as your doctor has prescribed. Try not to miss any doses. - If you find that the usual dose of BRIMICA 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. - Call your doctor straight away if you become pregnant while using BRIMICA GENUAIR 340/12.
Things you should not do	- Do not exceed the recommended daily dose. - Do not take any other medicines for your breathing problems without checking with your doctor.
Driving or using machines	- Be careful before you drive or use any machines or tools. - BRIMICA GENUAIR 340/12 may cause headache, dizziness, or blurred vision in some people.
Looking after your medicine	- Keep the inhaler protected in the sealed pouch until you need to start using it. - The inhaler must be used within 60 days of opening the pouch. - Keep your inhaler in a cool dry place where the temperature stays below 30C

For more information, see Section [5. What should I know while using BRIMICA GENUAIR 340/12?](#) in the full CMI.

6. Are there any side effects?

Common side effects include inflammation of the throat and nasal passages, headache, cough, diarrhoea, vomiting, inflammation of the sinuses, runny nose and sneezing, pain in the middle of the throat, urinary tract infection, dizziness, muscle spasms, fast or irregular heartbeat, tremor and throat irritation. Side effects that require urgent medical attention are serious allergic reactions which can include the following: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fast or irregular heart beat; or dizziness or fainting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

BRIMICA® GENUAIR® 340/12

Active ingredients: *aclidinium bromide / formoterol fumarate dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BRIMICA GENUAIR 340/12. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BRIMICA GENUAIR 340/12.**

Where to find information in this leaflet:

1. [Why am I using BRIMICA GENUAIR 340/12?](#)
2. [What should I know before I use BRIMICA GENUAIR 340/12?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use BRIMICA GENUAIR 340/12?](#)
5. [What should I know while using BRIMICA GENUAIR 340/12?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using BRIMICA GENUAIR 340/12?

BRIMICA GENUAIR 340/12 contains two active ingredients **aclidinium bromide and formoterol fumarate dihydrate**. BRIMICA GENUAIR 340/12 belongs to a group of medicines known as bronchodilators, which 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.

BRIMICA GENUAIR 340/12 is used for maintenance treatment of your COPD; 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.

2. What should I know before I use BRIMICA GENUAIR 340/12?

Warnings

BRIMICA GENUAIR 340/12 is a maintenance bronchodilator and should not be used for the relief of acute episodes of bronchospasm, including a sudden attack of breathlessness or wheezing.

Do not use BRIMICA GENUAIR 340/12 if:

- you are allergic to aclidinium bromide, formoterol fumarate dihydrate, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

Have or have had any other medical conditions:

- asthma
- heart problems
- epilepsy
- thyroid gland problems
- a tumour in one of your adrenal glands
- difficulty passing urine
- see halos around lights and coloured images, have eye pain or discomfort or temporary blurring of vision (narrow angle glaucoma)
- an enlarged prostate, problems passing urine, or a blockage in your bladder
- rare hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption
- take any medicines for any other condition

BRIMICA GENUAIR 340/12 may cause dryness in the mouth, which may cause tooth decay after using your medicine for a long time. Therefore, please remember to pay attention to oral hygiene.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 adolescence

- BRIMICA GENUAIR 340/12 is not for use in children or adolescents below 18 years of age.

3. What if I am taking other medicines?

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

Some medicines may interfere with BRIMICA GENUAIR 340/12 and affect how it works.

These include:

- Other medicines used to treat breathing difficulties
- Medicines that lower the amount of potassium in your blood
 - steroids that you take by mouth such (such as 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 (such as anti-histamines)

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BRIMICA GENUAIR 340/12.

4. How do I use BRIMICA GENUAIR 340/12?

How much to use

- The recommended dose is one inhalation twice a day in the morning and night, 12 hours apart.
- Follow the instructions provided and use BRIMICA GENUAIR 340/12 until your doctor tells you to stop.

When to use BRIMICA GENUAIR 340/12

- BRIMICA GENUAIR 340/12 should be used at the same time every morning and night as the effects last for 12 hours. This ensures that there is always enough medicine in your body to help you breathe more easily throughout the day and night.

How to use BRIMICA GENUAIR 340/12

- Refer to the booklet contained within the carton for instructions on how to use the BRIMICA GENUAIR 340/12 inhaler.

You can also find instructions on how to use the BRIMICA GENUAIR 340/12 inhaler online:

The Instructions for Use leaflet is available here:

<https://medsinfo.com.au/media/fkibring>

The Instructions for Use video is available here:

<https://medsinfo.com.au/media/fkvgenua>

- If you are not sure of how to use BRIMICA GENUAIR 340/12, ask your doctor or pharmacist

If you forget to use BRIMICA GENUAIR 340/12

BRIMICA GENUAIR 340/12 should be used regularly at the same time each day. If you miss your dose at the usual time, inhale the dose as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

If you are not sure what to do, ask your doctor or pharmacist

If you use too much BRIMICA GENUAIR 340/12

If you think that you have used too much BRIMICA GENUAIR 340/12, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BRIMICA GENUAIR 340/12?

Things you should 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 find that the usual dose of BRIMICA 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.

Call your doctor straight away if you:

- Become pregnant while using this medicine

Remind any doctor, dentist or pharmacist you visit that you are using BRIMICA 340/12, especially if you are about to be started on any new medicine.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not exceed the recommended daily dose.

- Do not take any other medicines for your breathing problems without checking with your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use BRIMICA GENUAIR 340/12 to treat other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BRIMICA GENUAIR 340/12 affects you.

BRIMICA GENUAIR 340/12 may cause headache, dizziness, or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Looking after your medicine

- Keep the BRIMICA GENUAIR 340/12 inhaler protected in the sealed pouch until you need to start using it.
- Keep your inhaler below 30°C.

Follow the instructions provided on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

The inhaler must be used within 60 days of opening the pouch.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Stomach-related: • diarrhoea, vomiting, nausea or abdominal discomfort Head-related: • headache • unable to sleep • fatigue	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• dizziness • trembling, shakiness or agitation • nervousness or anxiety Mouth, throat, nose and airways - related: • inflammation of the sinuses (sinusitis) • runny nose or sneezing (rhinitis) • common cold or flu symptoms • cough • increased mucous (sputum) • dry mouth • changes in voice • changes in sense of taste • sore mouth or throat from inhaling the powder or irritation in the throat • painful swelling and sores inside the mouth • infection in the tissues at the base of a tooth (tooth abscess) Injury-related: • fall (as a result of dizziness) Skin-related: • bacterial skin infection (cellulitis) • itchy skin • rash Muscle-related: • muscle aching, cramps or spasms • muscle-related joint pain and stiffness Heart and chest-related: • fast or irregular heartbeat • chest pain Eyes-related: • blurred vision Ears-related: • earwax blockage Infection-related: • yeast infection	

Serious side effects

Serious side effects	What to do
Allergy-related: • swelling of the face, lips, tongue, throat, eyes or other part of the body; difficulty in breathing, palpitations, severe dizziness or	Call your doctor straight away, or go straight to the Emergency Department at

Serious side effects	What to do
fainting; redness, itching or rash on the skin General body-related: - swelling of the hands, feet or ankles (known as angioedema) Airway-related: - tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine. These may be signs of a condition called paradoxical bronchospasm. Heart-related: - fast, abnormal or irregular heartbeat (cardiac arrhythmias) Bladder-related: - painful and/or frequent urination - difficulty passing urine - blood in urine	your nearest hospital if you notice any of these serious side effects.

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

Other side effects not listed here may occur in some people. Some of these side effects (abnormal blood test results including high blood sugar levels) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What BRIMICA GENUAIR 340/12 contains

Active ingredient (main ingredient)	396 micrograms acclidinium bromide and 12 micrograms formoterol fumarate dihydrate.
Other ingredients (inactive ingredients)	Lactose monohydrate
Potential allergens	Lactose

Do not take this medicine if you are allergic to any of these ingredients.

What BRIMICA GENUAIR 340/12 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.

(AUST R 224899).

Who distributes BRIMICA GENUAIR 340/12

A. Menarini Australia Pty Ltd
Sydney, Australia

Medical Information: 1800 644 542

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For the most up to date version of this document, please go to www.menarini.com.au/cmi

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