

ENERZAIR® BREEZHALER®

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using ENERZAIR BREEZHALER?

ENERZAIR BREEZHALER contains the active ingredients indacaterol, glycopyrronium and mometasone furoate. ENERZAIR BREEZHALER is used as a maintenance treatment of asthma in adult patients.

For more information, see Section [1. Why am I using ENERZAIR BREEZHALER?](#) in the full CMI.

2. What should I know before I use ENERZAIR BREEZHALER?

Do not use if you have ever had an allergic reaction to ENERZAIR BREEZHALER 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 ENERZAIR BREEZHALER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ENERZAIR BREEZHALER 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 ENERZAIR BREEZHALER?

- Your doctor will advise you of the appropriate dose.
- Inhale the contents of one capsule once daily.

More instructions can be found in Section [4. How do I use ENERZAIR BREEZHALER?](#) in the full CMI.

5. What should I know while using ENERZAIR BREEZHALER?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are

	<p>using ENERZAIR BREEZHALER</p> <ul style="list-style-type: none"> • Use this medicine exactly as prescribed by your doctor or pharmacist • Tell your doctor immediately if you become pregnant or intend to become pregnant
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly • Do not use this medicine to treat any other problems unless your doctor tells you to • Do not swallow ENERZAIR BREEZHALER capsules
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how ENERZAIR BREEZHALER affects you
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol

Looking after your medicine	<ul style="list-style-type: none"> • Do not store above 30°C • The capsules must always be stored in the blister pack to protect them from moisture and light
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For more information, see Section [5. What should I know while using ENERZAIR BREEZHALER?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include headache, rash, hives, itchiness, dry mouth, fever, feeling tired, muscle cramps, abnormal heart rhythm, throat irritation, cough, hoarse voice, white tongue, pain in muscles, bones, joints, muscle cramp, back pain, neck pain, aching muscles, muscle weakness, frequent urge to urinate, pain or burning when urinating, vomiting or feeling sick. Serious side effects include trouble breathing, wheezing, swelling of face, tongue, eyes, difficulty swallowing, blisters on face, changes to vision, tightness in chest, chest pain, fast heart rate.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ENERZAIR® BREEZHALER®

Active ingredient(s): *Indacaterol/glycopyrronium/mometasone furoate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ENERZAIR BREEZHALER. **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 ENERZAIR BREEZHALER.**

Where to find information in this leaflet:

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

1. Why am I using ENERZAIR BREEZHALER?

ENERZAIR BREEZHALER contains the active ingredients indacaterol, glycopyrronium and mometasone furoate.

Indacaterol and glycopyrronium belong to a group of medicines called bronchodilators. They help to relax the muscles around your airways in the lungs. This makes breathing easier in asthma patients.

Mometasone furoate belongs to a group of medicines called corticosteroids which help to reduce swelling and irritation in your airways in the lungs. It also helps to prevent asthma attacks.

ENERZAIR BREEZHALER is used as a maintenance treatment of asthma in adult patients. It is used in patients who have not achieved adequate control with a maintenance combination of a long-acting beta2-agonist drug and an inhaled corticosteroid medicine who have experienced one or more asthma attacks in the previous year.

Asthma is a chronic lung disorder characterised by narrowing and swelling of airways which can cause difficulty in breathing. Its symptoms include wheezing, cough and shortness of breath.

2. What should I know before I use ENERZAIR BREEZHALER?

Warnings

Do not use ENERZAIR BREEZHALER if:

- you are allergic to indacaterol, glycopyrronium, mometasone furoate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Allergic reaction symptoms include swelling of the tongue, lips, and face; difficulty in breathing or swallowing, hives, or skin rash.

- you have acute asthma symptoms or acute episodes of bronchospasm (constriction of the airways).

Do not give this medicine to a child or adolescent under 18 years of age.

Check with your doctor if you:

- have any liver problems
- have any kidney problems, severe renal impairment or end-stage renal disease.
- have any heart problems including symptoms such as increase in pulse rate, high blood pressure
- take any medicines for diabetes or have a high blood sugar level

- have eye problems such as narrow-angle glaucoma (an eye disorder that causes damage to the optic nerve of the eye)
- have any problems regarding your urinary bladder (urinary retention)
- have pulmonary tuberculosis or any chronic or untreated infections
- have a low level of potassium in your blood
- have any thyroid problems
- suffer from fits/seizures

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.

Your doctor will advise you regarding the possible risks and benefits of using ENERZAIR BREEZHALER during pregnancy.

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

It is unknown whether the active ingredients in ENERZAIR BREEZHALER pass into breast milk.

Your doctor will advise you regarding the possible risks and benefits of using ENERZAIR BREEZHALER during breast feeding.

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 ENERZAIR BREEZHALER and affect how it works.

Tell your doctor/pharmacist if you take any of the following medications:

- Medicines used to treat depression such as monoamine oxidase inhibitors, tricyclic antidepressants
- Medicines used to treat high blood pressure or lower the level of potassium in your blood such as diuretics.
- Bronchodilator medications such as methylxanthines used to treat breathing problems (e.g. theophylline) or steroids (e.g. prednisolone)
- Medicines used to treat other heart problems, (e.g. propranolol) or to treat glaucoma (e.g. timolol)
- Medicines used to treat fungal infections (e.g., ketoconazole or itraconazole)
- Medicines used in the treatment of HIV infection (e.g., ritonavir, nelfinavir or cobicistat)
- Medicines that are used to treat low heart rate, respiratory problems (muscarinic antagonists or long-acting beta2-adrenergic agonists)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ENERZAIR BREEZHALER.

4. How do I use ENERZAIR BREEZHALER?

How much to use

- There are two dose strengths of ENERZAIR Breezhaler, 114/46/68 micrograms and 114/46/136 micrograms. Your doctor will decide which dose is appropriate for you
- Follow the instructions provided and use ENERZAIR BREEZHALER until your doctor tells you to stop
- Inhale the contents of one capsule of ENERZAIR BREEZHALER each day

When to use ENERZAIR BREEZHALER

- ENERZAIR BREEZHALER should be used at about the same time each day

How to use ENERZAIR BREEZHALER

- Follow the instructions provided by your doctor and use ENERZAIR BREEZHALER carefully
- Use it only for inhalation
- **Do not swallow ENERZAIR BREEZHALER capsules.**

- The capsules must be used only using the ENERZAIR BREEZHALER inhaler
- The inhaler is provided with each new prescription
- Keep the capsules in the blister and only remove them before using
- Peel the backing away from the blister to open it; do not push the capsule through the foil
- After inhalation, rinse your mouth with water without swallowing
- **If you do not understand how to use the inhaler, ask your doctor or pharmacist for advice**

If you forget to use ENERZAIR BREEZHALER

ENERZAIR BREEZHALER 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 possible. Then inhale the next dose at the usual time.

Do not take more than one dose in a day.

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.

If you use too much ENERZAIR BREEZHALER

If you think that you have used too much ENERZAIR BREEZHALER, 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 ENERZAIR BREEZHALER?

Things you should do

Call your doctor straight away if you:

- Develop any allergic reaction to ENERZAIR BREEZHALER.
- Experience any side effects to ENERZAIR BREEZHALER or have any asthma attacks.
- Are pregnant or intend to become pregnant.
- Have any liver, kidney or heart problems.

Use this medicine exactly as prescribed by your doctor or pharmacist.

Only use the inhaler provided in the pack. You will receive a new inhaler each time you refill your script.

You may discard your old inhaler when the capsules are finished.

Remind any doctor, dentist or pharmacist you visit that you are using ENERZAIR BREEZHALER.

Things you should not do:

- Do not stop using this medicine suddenly
- Do not swallow ENERZAIR BREEZHALER capsules
- Do not use this medicine to treat any other problems unless your doctor tells you to
- Do not give your medicine to anyone else (especially children), even if they have the same condition as you

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ENERZAIR BREEZHALER affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Follow the instructions provided in the user leaflet on how to properly clean and take care of your ENERZAIR BREEZHALER
- Do not store above 30°C
- Dispose of each BREEZHALER inhaler after 30 days of use

The capsules must always be stored in the blister to protect them from moisture and light.

Remove the capsules only before use

Follow the instructions in the carton on how to take care of your medicine properly

Store 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.

Getting rid of any unwanted medicine

Discard your ENERZAIR BREEZHALER when you have no capsules left.

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.

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
<p>General problems:</p> <ul style="list-style-type: none"> • Headache • Rash • Hives, itchiness • Dry mouth • Fever • Feeling tired, muscle cramps, abnormal heart rhythm (could be low level of potassium in your blood) <p>Respiratory problems:</p> <ul style="list-style-type: none"> • Throat irritation • Cough • Hoarse voice • White tongue <p>Muscle problems:</p> <ul style="list-style-type: none"> • Pain in muscles, bones, joints • Muscle cramp • Back pain • Neck pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Aching muscles, muscle weakness not caused by exercise <p>Infections:</p> <ul style="list-style-type: none"> • A frequent urge to urinate and pain or burning when urinating (signs of urinary tract infection) <p>Tummy problems:</p> <ul style="list-style-type: none"> • Vomiting, feeling sick, pain in tummy 	

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction</p> <ul style="list-style-type: none"> • Trouble breathing, wheezing • Swelling of face, tongue, eyes • Difficulty swallowing. • Blisters on face, lips that are spreading. <p>Eye problems</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Changes to vision or blurred vision Heart problems: <ul style="list-style-type: none"> • Tightness in chest, chest pain • Fast heart rate that may make you feel faint 	

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.

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 ENERZAIR BREEZHALER contains

Active ingredient (main ingredient)	Indacaterol/ glycopyrronium/ mometasone furoate
Other ingredients (inactive ingredients)	Capsule fill: Lactose monohydrate, Magnesium stearate. Capsule shell components: Hypromellose, Purified water, Carrageenan, Potassium chloride. Colourants: Iron oxide yellow, Indigotine.
Potential allergens	lactose (as monohydrate)

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

What ENERZAIR BREEZHALER looks like

The pack contains a white plastic BREEZHALER inhaler device together with capsules in blister cards.

ENERZAIR BREEZHALER has two strengths based on the amount of medicine in each:

ENERZAIR BREEZHALER 114/46/68 micrograms, inhalation powder, hard capsules have green transparent cap and uncoloured transparent body containing a white to practically white powder, with the product code “IGM150-50-80” printed in black on the body and with a logo printed in white on the cap (AUST R 319002)

ENERZAIR BREEZHALER 114/46/136 micrograms, inhalation powder, hard capsules have green transparent cap and uncoloured transparent body containing a white to practically white powder, with the product code “IGM150-50-160” printed in black above two black bars on the body and with a logo printed in black and surrounded by one black bar on the cap (AUST R 319001)

Who distributes ENERZAIR BREEZHALER

ENERZAIR BREEZHALER is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Web site: www.novartis.com.au

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