

RILAST RAPIHALER™

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 Rilast Rapihaler?

Rilast Rapihaler contains two active ingredients in one inhaler: budesonide and formoterol fumarate dihydrate. Rilast Rapihaler is used for treatment of asthma in adults and adolescents (12 years and over) or Chronic Obstructive Pulmonary Disease (COPD) in adults (18 years and over).

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

2. What should I know before I use Rilast Rapihaler?

Do not use if you have ever had an allergic reaction to any medicine containing budesonide or formoterol, 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 Rilast Rapihaler?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rilast Rapihaler 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 Rilast Rapihaler?

- Rilast Rapihaler should be inhaled into your lungs through the mouth.
- Follow all directions given to you by your doctor or pharmacist.

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

5. What should I know while using Rilast Rapihaler?

Things you should do	<ul style="list-style-type: none">• If you have an Asthma Action Plan agreed with your doctor, follow it closely at all times.• Have your reliever medicine available at all times. As advised by your doctor, this may be your Rilast Rapihaler 100/3 or another reliever medicine.• Rinse your mouth out with water after taking your daily morning and/or evening dose of Rilast Rapihaler and spit this out.• Remind any doctor, dentist or pharmacist you visit that you are using Rilast Rapihaler.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without checking with your doctor
Driving or using machines	<ul style="list-style-type: none">• Rilast Rapihaler may cause dizziness, light-headedness, tiredness or drowsiness in some people when they first start using it.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Rilast Rapihaler in a cool dry place where the temperature stays below 30°C, with the cover firmly in place.• Dispose your Rilast Rapihaler 3 months after removal from the foil pouch.

For more information, see Section [5. What should I know while using Rilast Rapihaler?](#) in the full CMI.

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. These include sore, yellowish, raised patches in the mouth (thrush), hoarse voice, unpleasant taste in your mouth, pounding heart, headache, trembling or muscle cramps. However, some side effects may need medical attention. These include severe allergic reactions such as difficulty breathing, swelling of the face, lips or tongue, severe rash or pneumonia (lung infection), signs include fever or chills, increased phlegm or a change in colour, increased cough or difficulties breathing. Serious side effects are rare.

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.

RILAST RAPIHALER™

Active ingredient(s): *budesonide / formoterol fumarate dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Rilast Rapihaler. **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 Rilast Rapihaler.**

Where to find information in this leaflet:

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

1. Why am I using Rilast Rapihaler?

Rilast Rapihaler is a pressurised metered dose inhaler (pMDI) or puffer. It contains two active ingredients in one inhaler: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called corticosteroids. Budesonide acts directly on your airways to reduce inflammation.
- Formoterol belongs to a group of medicines called beta-2-agonists. Formoterol opens up the airways to help you breathe more easily.

The medicine inside Rilast Rapihaler is inhaled into the lungs for the treatment of asthma in adults and adolescents (12 years and over) or Chronic Obstructive Pulmonary Disease (COPD) in adults (18 years and over).

Asthma

Asthma is a disease where the airways of the lungs become narrow and inflamed (swollen), making it difficult to breathe. This may for example be due to exercise, or exposure to allergens (e.g. an allergy to house dust mites, smoke or air pollution), or other things that irritate your lungs.

The budesonide in Rilast Rapihaler helps to improve your condition and to prevent asthma attacks from occurring.

The formoterol in Rilast Rapihaler helps you breathe more easily.

Some people can take Rilast Rapihaler when they need it – they use Rilast Rapihaler as an anti-inflammatory reliever to treat their symptoms when their asthma gets worse and to help prevent asthma attacks, or to help prevent symptoms from happening (eg before exercise or exposure to other triggers such as allergens).

Some people need to take Rilast Rapihaler every day – they use their Rilast Rapihaler as a daily maintenance preventer to help maintain control of their asthma symptoms and help prevent asthma attacks.

Chronic Obstructive Pulmonary Disease (COPD)

COPD (which includes chronic bronchitis and emphysema) is a long-term lung disease. There is often permanent narrowing and persistent inflammation of the airways. Symptoms may include difficulty in breathing (breathlessness or wheezing), coughing and increased sputum (phlegm).

Rilast Rapihaler 200/6 when used as prescribed will help to control your COPD symptoms (ie breathing difficulties).

2. What should I know before I use Rilast Rapihaler

Warnings

Do not use Rilast Rapihaler if:

- you are allergic to any medicine containing budesonide or formoterol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any allergies to any other medicines or foods.
- have, or have had, any of the following medical conditions, as it may not be safe for you to take Rilast Rapihaler:
 - thyroid problems
 - diabetes
 - heart problems
 - liver problems
 - tuberculosis (TB)
 - low levels of potassium in the blood.
- currently have an infection. If you take Rilast Rapihaler while you have an infection, the medicine may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.
- have any other medical conditions.
- have any questions about how you should be using your Rilast Rapihaler.

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.

Your doctor will discuss the possible risks and benefits of using Rilast Rapihaler during pregnancy and while breastfeeding.

Children

Do not give Rilast Rapihaler to a child under 12 years, unless directed to by the child's doctor.

Rilast Rapihaler is not recommended for use in children under 12 years.

Asthma Action Plan

If you have asthma, ask your doctor or pharmacist if you have any questions about your Asthma Action Plan.

Your healthcare professional should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take as a reliever when you have symptoms or sudden attacks of asthma, medicines you can take to prevent symptoms from occurring (eg prior to exercise or allergen exposure) and if you need to take daily maintenance medicines to help control your asthma. It will also provide advice on when to seek urgent medical attention such as when your asthma suddenly worsens or worsens over a period of time.

It is important that you discuss with your doctor both your exposure to triggers and how often you exercise, as these could impact how your doctor prescribes your Rilast Rapihaler.

3. What if I am taking other medicines?

Some medicines may interfere with Rilast Rapihaler and affect how it works. These include:

- medicines used to treat heart problems or high blood pressure such as beta-blockers, diuretics and antiarrhythmics (disopyramide, procainamide and quinidine)
- medicines used to treat glaucoma such as beta-blockers
- medicines used to treat depression or other mood/mental disorders such as tricyclic antidepressants, monoamine oxidase inhibitors and phenothiazines
- medicines used to treat hayfever, coughs, colds and runny nose such as antihistamines
- medicines used to treat fungal infections (eg ketoconazole)
- xanthine derivatives (eg theophylline) which are a class of medicines used to treat asthma and COPD
- medicines used to treat Addison's disease (when there is inadequate production of a natural steroid hormone by the adrenal gland) or another condition where there is too much salt loss in the urine (eg fludrocortisone)

These medicines may be affected by Rilast Rapihaler or may affect how well it works. You may need different amounts of your medicine, or you may need to use different medicines. Your doctor or pharmacist will advise you.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Rilast Rapihaler.

4. How do I use Rilast Rapihaler?

How to use your Rilast Rapihaler

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

They may differ from the information contained in this leaflet.

Each pack of Rilast Rapihaler contains an instruction for use leaflet that tells you the correct way to use it. Please read this carefully.

If you are not sure how to use the Rilast Rapihaler, ask your doctor or pharmacist to show you how.

How much to take

Asthma (Adults and children 12 years and over)

Your healthcare professional should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take as a reliever when you have symptoms or sudden attacks of asthma, medicines you take prevent symptoms from occurring (eg prior to exercise or allergen exposure) and if you need to take daily maintenance medicines to help control your asthma.

It is important that you discuss with your doctor both your exposure to triggers and how often you exercise, as these could impact how your doctor prescribes your Rilast Rapihaler.

Your doctor may have prescribed Rilast Rapihaler for you to use as:

- an anti-inflammatory reliever medicine only,
- both an anti-inflammatory reliever and daily maintenance preventer medicine or,
- as a daily maintenance preventer only, where another medicine is used as a reliever.

If your asthma has been under control for some time, your doctor may tell you to take less inhalations of Rilast Rapihaler, prescribe you a lower strength of Rilast Rapihaler or recommend that you use Rilast Rapihaler in a different way.

If you are using more inhalations of your reliever medicine or you are wheezing or breathless more than usual tell your doctor as your asthma may be getting worse.

Ask your doctor if you have any questions about how you should be using your Rilast Rapihaler.

Anti-inflammatory reliever only (Rilast Rapihaler 100/3)

For patients aged 12 years and over, Rilast Rapihaler 100/3 can be used to treat asthma symptoms when they happen and to help stop asthma symptoms from happening (eg just before exercise or before you get exposed to other triggers).

If you get asthma symptoms, take 2 inhalations and wait a few minutes. If you do not feel better, take 2 more inhalations.

Your doctor will tell you how many inhalations to take before exercising or exposure to other triggers to help stop symptoms from happening.

Do not use more than 12 inhalations on a single occasion or more than 24 inhalations in any day. If your symptoms continue to worsen over 3 days, despite using additional inhalations, tell your doctor.

Have your Rilast Rapihaler reliever with you at all times.

Anti-inflammatory reliever plus maintenance therapy (Rilast Rapihaler 100/3)

For patients aged 12 years and over, Rilast Rapihaler 100/3 can be used to treat asthma symptoms when they happen. Rilast Rapihaler 100/3 can also be used to help stop asthma symptoms from happening (eg just before exercise or before you get exposed to other triggers).

If you get asthma symptoms, take 2 inhalations of Rilast Rapihaler 100/3 and wait a few minutes. If you do not feel better, take 2 more inhalations.

Your doctor will tell you how many inhalations of Rilast Rapihaler 100/3 to take before exercising or exposure to other triggers to help stop symptoms from happening.

Have your Rilast Rapihaler 100/3 reliever with you at all times.

You also need to take your Rilast Rapihaler 100/3 daily as your maintenance preventer. The usual maintenance dose is 4 inhalations per day (given either as 2 inhalations in the morning and evening or as 4 inhalations in either the morning or evening). Your doctor may prescribe a maintenance dose of Rilast Rapihaler 100/3, 4 inhalations twice a day.

Do not use more than 12 inhalations on a single occasion or more than 24 inhalations of Rilast Rapihaler 100/3 (as needed and daily dose) in any day. If your symptoms continue to worsen over 3 days, despite using additional inhalations, tell your doctor.

NOTE: Rilast Rapihaler 200/6 is not recommended to be used as anti-inflammatory reliever medicine.

Daily fixed dose maintenance therapy (Rilast Rapihaler 100/3 and 200/6)

For patients aged 12 years and over, Rilast Rapihaler 100/3 or 200/6 can be used as a daily fixed-dose maintenance preventer.

The usual dose of Rilast Rapihaler 100/3 is 2 or 4 inhalations twice a day. Do not take more than 8 inhalations a day.

The usual dose of Rilast Rapihaler 200/6 is 2 inhalations twice a day. Do not take more than 4 inhalations a day.

Rilast Rapihaler 200/6 can also be given as a higher dose in patients aged 18 years and over. The usual dose is 4 inhalations twice a day. Do not take more than 8 inhalations per day.

Have your separate reliever with you at all times.

COPD (Adults)

The usual dose (also maximum recommended dose) is 2 inhalations of Rilast Rapihaler 200/6 twice a day.

Your doctor should tell you the best way to manage your symptoms and any flare ups. This may include additional medicines (such as reliever medicines) to use when you have sudden attacks of breathlessness.

If you are using more inhalations of your reliever medicine or you are wheezing or breathless more than usual tell your doctor.

If your COPD gets worse, your doctor may give you some additional medicines (such as oral corticosteroids or antibiotics).

How long to use your Rilast Rapihaler

If your doctor has told you to take Rilast Rapihaler daily, it is important that you use it every day even if you feel well.

Rilast Rapihaler helps control your asthma or COPD but does not cure it.

Keep using it for as long as your doctor tells you to. Do not stop using it unless your doctor tells you to.

If you forget to use Rilast Rapihaler

If you miss a dose of Rilast Rapihaler, take your dose as soon as you remember.

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

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

If you are using Rilast Rapihaler as a reliever medicine, consult your doctor on the correct use of the product.

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

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

If you use too much Rilast Rapihaler

If you think that you have used too much Rilast Rapihaler, 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.

If you use too much Rilast Rapihaler, you may feel sick or vomit, have a fast or irregular heartbeat, a headache, tremble, feel shaky, agitated, anxious, tense, restless, excited or be unable to sleep.

5. What should I know while using Rilast Rapihaler?

Things you should do

- If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.
- Keep using Rilast Rapihaler for as long as your doctor tells you to, even if you are feeling well.
- See your doctor regularly to make sure that your asthma or COPD is not getting worse.
- Have your reliever medicine available at all times. As advised by your doctor, this may be your Rilast Rapihaler 100/3 or another reliever medicine.
- If you become pregnant while using Rilast Rapihaler, tell your doctor.
- Rinse your mouth out with water after taking your daily morning and/or evening dose of Rilast Rapihaler and spit this out. If you don't rinse your mouth, you are more likely to develop thrush in your mouth. You do not have to rinse mouth if you have to take occasional doses of Rilast Rapihaler for relief of asthma symptoms (ie as an anti-inflammatory reliever).

Call your doctor straight away if you:

- are taking Rilast Rapihaler for COPD and you notice any signs of pneumonia (infection of the lung). Signs include fever or chills, increased phlegm/sputum production or change in colour, increased cough or increased breathing difficulties. Pneumonia is a serious medical condition and will require urgent medical attention.

Remind any doctor, dentist or pharmacist you visit that you are using Rilast Rapihaler.

Things you should not do

- Do not stop using this medicine suddenly without checking with your doctor.
- Do not take any other medicines for your asthma or COPD without checking with your doctor.
- Do not give Rilast Rapihaler to anyone else, even if they have the same condition as you.
- Do not use Rilast Rapihaler to treat any 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 Rilast Rapihaler affects you.

Rilast Rapihaler may cause dizziness, light-headedness, tiredness or drowsiness in some people when they first start using it.

Looking after your medicine

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

Storage

Keep your Rilast Rapihaler in a cool dry place where the temperature stays below 30°C.

Always replace the mouthpiece cover after using Rilast Rapihaler.

Discard Rilast Rapihaler within 3 months after removal from the foil pouch.

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.

WARNING

The canister in Rilast Rapihaler contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister. The canister should not be broken, punctured or burnt, even when it seems empty.

Cleaning

The Rilast Rapihaler mouthpiece must be wiped with a clean dry cloth/tissue and must never get wet.

Full instructions on the right way to use and clean Rilast Rapihaler are inside each pack.

Getting rid of any unwanted medicine

Since some medicine may remain inside your Rilast Rapihaler you should always return it to your pharmacist for disposal including:

- when you have taken all your doses and the dose counter is on zero ('0' - see instructions in the pack), or
- 3 months after removal from the foil pouch, or
- it is damaged or past its expiry date, or
- your doctor/pharmacist has told you to stop using it.

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.

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

If you get any side effects, do not stop using Rilast Rapihaler without first talking to your doctor or pharmacist.

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
Mouth/throat-related: <ul style="list-style-type: none">• sore, yellowish, raised patches in the mouth (thrush)• hoarse voice• irritation of the tongue and mouth• coughing	These are less likely to happen if you rinse your mouth out after every time you use your usual morning and/or evening dose of Rilast Rapihaler.

Less serious side effects	What to do
	Speak to your doctor if you have any of these less serious side effects and they worry you.
Heart-related: <ul style="list-style-type: none"> fast or irregular heart rate or pounding heart chest pain Nervous system-related: <ul style="list-style-type: none"> feeling anxious, nervous, restless or upset headache trembling or shakiness feeling light-headed or dizzy thirsty unpleasant taste in your mouth tiredness Gut-related: <ul style="list-style-type: none"> nausea (feeling sick) diarrhoea Skin-related: <ul style="list-style-type: none"> skin rash skin bruising Others: <ul style="list-style-type: none"> difficulty sleeping muscle twitching or cramps weight gain 	Speak to your doctor if you have any of these less serious side effects and they worry you.
<ul style="list-style-type: none"> mood changes 	Speak to your doctor if you notice any of these. You may need urgent medical attention.

Serious side effects

Serious side effects	What to do
Allergic Reaction: <ul style="list-style-type: none"> difficulty breathing or worsening of your breathing problems swelling of the face, lips, tongue or other parts of the body severe rash Pneumonia (lung infection): <ul style="list-style-type: none"> signs include fever or chills, increased phlegm/sputum production or a change in 	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.

Serious side effects	What to do
colour, increased cough or difficulties breathing	You may need urgent medical attention. Serious side effects are rare.
Potential eye problem: Any issues with your eyes such as blurred vision or other problems with your eyesight.	Speak to your doctor if you notice any of these. Your doctor may need to send you to an ophthalmologist (eye doctor) to check that you don't have eye problems such as cataracts (clouding of the eye lens), glaucoma (increased pressure in your eyeballs) or other rare eye conditions reported with corticosteroids use.

Other side effects

Growth

Corticosteroids taken into the lungs for long periods (eg 12 months) may affect how children/adolescents grow. In rare cases, some children/adolescents may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a child's/adolescent's height.

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 (for example, changes in blood sugars) can only be found when your doctor does test 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 Rilast Rapihaler contains

Active ingredients (main ingredient)	<ul style="list-style-type: none">• budesonide• formoterol fumarate dihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• apaflurane (HFA-227)• macrogol 1000• povidone

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

Rilast Rapihaler does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What Rilast Rapihaler looks like

Rilast Rapihaler is a pressurised metered dose inhaler with a dose counter. The inhaler is comprised of a pressurised aluminum canister with an attached dose counter, a red plastic casing body with a white mouthpiece and attached grey mouthpiece cover. Each inhaler is individually wrapped in a foil laminate pouch (containing a sachet of drying agent).

Rilast Rapihaler is available in the following presentations*:

- 100/3: Each pack contains 1 inhaler of 120 inhalations of the medicine. [AUST R 396688]
- 200/6: Each pack contains 1 inhaler of 120 inhalations of the medicine. [AUST R 396689]

*not all presentations might be available in Australia

Who distributes Rilast Rapihaler

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