

SALFLUMIX EASYHALER®

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 SALFLUMIX EASYHALER?

SALFLUMIX EASYHALER contains the active ingredients fluticasone propionate and salmeterol. SALFLUMIX EASYHALER is used to help prevent breathing problems such as Asthma and Chronic Obstructive Pulmonary Disease (COPD).

DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help you. If that happens you need to use a fast acting 'reliever' medication.

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

2. What should I know before I use SALFLUMIX EASYHALER?

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

3. What if I am taking other medicines?

Some medicines may interfere with SALFLUMIX EASYHALER 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 SALFLUMIX EASYHALER?

- SALFLUMIX EASYHALER should be used twice daily.
- Use SALFLUMIX EASYHALER every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

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

5. What should I know while using SALFLUMIX EASYHALER?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, surgeon, anaesthetist or pharmacist you visit that you are using SALFLUMIX EASYHALER.• Rinse your mouth after using SALFLUMIX EASYHALER
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">• SALFLUMIX EASYHALER is unlikely to affect your ability to drive or use machinery but you should be careful until you know how SALFLUMIX EASYHALER affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store SALFLUMIX EASYHALER below 25°C and protect from moisture.• Keep the inhaler in the foil bag until you are ready to start using it.• Place the inhaler in the protective cover provided after you take it out of the foil bag.

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

6. Are there any side effects?

Common side effects include sore, yellowish, raised patches in the mouth (thrush); shakiness; headache and rapid heartbeat. Tell your doctor if you notice you feel more wheezy, your chest may feel tight more often or you have increased coughing or breathing problems.

Some side effects can only be found when your doctor does tests from time to time to check your progress.

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.

SALFLUMIX EASYHALER®

Active ingredients: *Fluticasone propionate and Salmeterol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SALFLUMIX EASYHALER. **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 SALFLUMIX EASYHALER.**

Where to find information in this leaflet:

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

1. Why am I using SALFLUMIX EASYHALER?

SALFLUMIX EASYHALER contains two active ingredients, fluticasone propionate and salmeterol.

- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.
- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for up to 12 hours.

SALFLUMIX EASYHALER is used to help prevent breathing problems such as:

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD)

SALFLUMIX EASYHALER helps to **prevent** breathlessness and wheeziness in people who need regular treatment.

DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help you. If that happens you need to use a fast acting 'reliever' medication, such as salbutamol.

2. What should I know before I use SALFLUMIX EASYHALER?

Warnings

Do not use SALFLUMIX EASYHALER if:

- you are allergic to fluticasone propionate, salmeterol xinafoate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

If you have breathing difficulties or wheezing that get worse straight after using SALFLUMIX EASYHALER stop using your SALFLUMIX EASYHALER inhaler. Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**

Check with your doctor if you:

- have or have had any other medical conditions especially the following:
 - thrush in your mouth
 - tuberculosis
 - diabetes
 - a thyroid condition
 - high blood pressure
 - heart problems including an irregular or fast heartbeat
 - low blood potassium levels
- take any medicines for any other condition

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.

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 SALFLUMIX EASYHALER and affect how it works.

Tell your doctor about any other medicines you are taking especially the following:

- Beta-blockers (such as atenolol, metoprolol, propranolol) used to treat high blood pressure and other heart conditions
- Ketoconazole, a medicine used to treat fungal infections
- Ritonavir, a medicine used to treat HIV infection.
- Any other steroid medicines (taken by mouth or as an injection) used to treat swelling, inflammation or breathing problems.

These medicines may be affected by SALFLUMIX EASYHALER or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How do I use SALFLUMIX EASYHALER?

How much to use

Use SALFLUMIX EASYHALER every day, until your doctor advises you to stop

Follow the instructions provided and use SALFLUMIX EASYHALER until your doctor tells you to stop. Do not exceed the recommended dose. Check with your doctor or pharmacist if you are not sure.

For Asthma

Adults and children over 12 years

- One inhalation of SALFLUMIX EASYHALER 250/50 or SALFLUMIX EASYHALER 500/50 twice daily.

For Chronic Obstructive Pulmonary Disease (COPD)

Adults

- One inhalation of SALFLUMIX EASYHALER 250/50 or SALFLUMIX EASYHALER 500/50 twice daily.

Easyhaler is not recommended for use in children below 12 years of age.

When to use SALFLUMIX EASYHALER

- SALFLUMIX EASYHALER should be used twice daily.
- You must use SALFLUMIX EASYHALER every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

If your asthma or breathing gets worse tell your doctor straight away. You may feel more wheezy, your chest may feel tight more often or you may need to use more of your fast acting 'reliever' medicine. If any of these happen, you should continue to take SALFLUMIX EASYHALER but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

How to use SALFLUMIX EASYHALER

SALFLUMIX EASYHALER is for inhalation through the mouth only.

SALFLUMIX EASYHALER is easy to use. Read through these instructions first: they tell you what you should do and what to look out for.

Unpack the inhaler

Take the inhaler out of its packaging. It comes in a laminate pouch to keep the powder dry. Only take it out of the pouch when you are ready to start using it.

The inhaler should come with a dust cap on the mouthpiece. **(Figure 1).** The carton will also include a protective cover.

After removal from the laminate pouch, you must fit the inhaler into its protective cover which helps improve the durability of the product. To fit the inhaler into the protective cover, open up the protective cover **(Figure 2a)**. Ensure the dustcap (dark purple/blue cap) covers the mouth-piece of inhaler (this stops the inhaler going off by accident) before inserting the inhaler into the protective cover. Close the protective cover until you hear a click to ensure tight seal

The inhaler should remain inside the protective cover at all times until dosing. **(Figure 2b)**

Discard the SALFLUMIX EASYHALER 250/50 inhaler 1 month after removal from the laminate pouch and the SALFLUMIX EASYHALER 500/50 inhaler 2 months after removal from the laminate pouch. The inhaler label includes a space for you to write the date of when you should discard the inhaler.

Figure 1

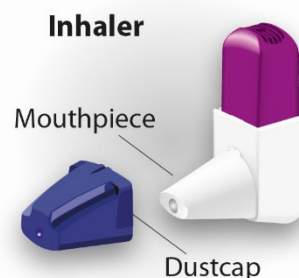


Figure 2a



Figure 2b



How to take a dose from SALFLUMIX EASYHALER

1. Shake

- Remove the dust cap.
- Hold the inhaler upright, gripping it between your finger and thumb
- Shake the device vigorously up and down three to five times. This is to make sure the powder flows properly and gives the correct dose (**Figure 3**).
- Make sure you shake it up and down and you do not click it while you shake it.

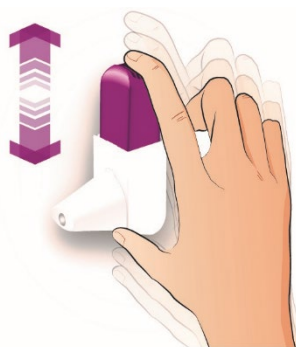


Figure 3

2. Click

- Make sure the dust cap is not on the inhaler, it will stop you clicking it.
- Still holding the inhaler upright, squeeze until you hear a click, and let it click back again. This delivers powder into the inhalation channel inside the mouthpiece (**Figure 4**).
- Only click down once, just before you take the medicine. If you click it more than once, see section *“If you have problems using the inhaler”*.
- Make sure you keep the inhaler upright as you click it and inhale the dose.

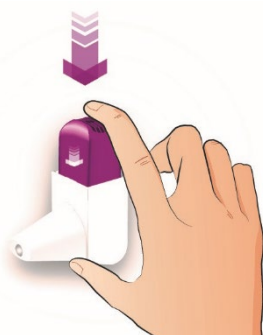


Figure 4

3. Inhale

In the sitting or standing position

- Breathe out normally
- Place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece to make a good seal (**Figure 5**).
- Make sure the whole mouthpiece is well inside your mouth, so the powder does not go on your teeth
- Take a strong and deep breath in
- Take the inhaler out of your mouth and hold your breath for about 5 seconds or for as long as it is comfortable, then breathe out gently away from the inhaler.
- Do not breathe out into the inhaler. This is important: it could clog up the inhaler. If you breathed out into the inhaler, see section *“If you have problems using the inhaler”*

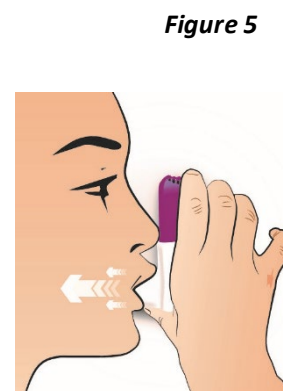


Figure 5

If you have problems using the inhaler

- Do not rush things. It is important to breathe normally. Practice a few times, in front of the mirror if this helps.
- If you click the inhaler by accident, or if you might have clicked it more than once, or if you breathe out into it, tap the mouthpiece to empty the powder onto a table top, or the palm of your hand (Figure 6). This ensures proper dosing. Then start again with steps 1, 2 and 3.

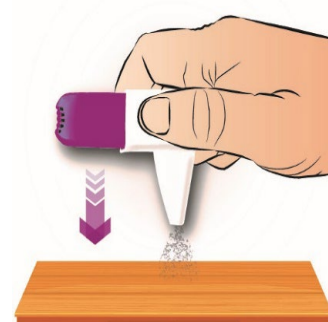


Figure 6

If you are to take a second inhalation

- Start again with steps 1, 2 and 3 (Note that you need to shake the device again as instructed in step 1).

After you have used the inhaler

- Put the dust cap back on the mouthpiece and close the protective cover.
- Rinse your mouth with water and spit it out after you use SALFLUMIX EASYHALER.

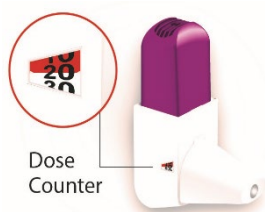
Cleaning the Easyhaler

- Clean the Easyhaler's mouthpiece at least once a week with a dry cloth. Do not use water: the powder in the Easyhaler is sensitive to moisture. You can take the Easyhaler out of it to wipe it. When you are putting it back into its protective cover, put the dust cap on the mouthpiece to stop it going off accidentally.

Getting a new Easyhaler

- The inhaler has a dose counter which shows how many doses are left. The counter turns after every fifth actuation (**Figure 7**). When the numbers go red, there are 20 doses left. If you do not already have a new Easyhaler, contact your doctor for a new prescription. When the counter reaches 0, you need to replace the Easyhaler.

Figure 7



For more information on how to use SALFLUMIX EASYHALER please visit www.orionpharma.com.au/patient.

If you forget to use SALFLUMIX EASYHALER

SALFLUMIX EASYHALER should be used regularly at the same time each 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 become wheezy or feel tight in the chest before the next dose is due, use a 'reliever inhaler' in the usual way. You should get relief from your 'reliever inhaler' within a few minutes.

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

If you use too much SALFLUMIX EASYHALER

If you think that you have used too much SALFLUMIX EASYHALER, 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.

The most common symptoms that may occur if you use too much SALFLUMIX EASYHALER are trembling, headache, breathing faster than usual a rapid heartbeat or increased levels of blood sugar.

5. What should I know while using SALFLUMIX EASYHALER?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using SALFLUMIX EASYHALER.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

- It may affect other medicines used during surgery.
- It is important that all doctors treating you are aware that you are on inhaled steroids. If your body is stressed by, for example, severe infection, surgical operation, an accident etc, you may need steroid tablets or injections for a time.

Rinse your mouth after using SALFLUMIX EASYHALER

- Some people find that their mouth, throat or tongue becomes sore or that their voice becomes hoarse after inhaling this medicine. It may be helpful to rinse your mouth with water and spit it out after using your SALFLUMIX EASYHALER. Tell your doctor but do not stop treatment unless told to do so.

Call your doctor straight away if you:

- experience a change in your vision

Things you should not do

- Do not stop using this medicine suddenly. If you stop using it suddenly, your condition may worsen, or you may have unwanted side effects. Check with your doctor before you stop using this medicine., if possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SALFLUMIX EASYHALER affects you.

Looking after your medicine

- Store SALFLUMIX EASYHALER below 25°C and protect from moisture.
- Keep the inhaler in the foil bag until you are ready to start using it.
- Place the inhaler in the protective cover when you take it out of the foil bag.

Follow the instructions in the carton 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

Replace your SALFLUMIX EASYHALER 250/50 inhaler 1 month after first opening the foil bag.

Replace your SALFLUMIX EASYHALER 500/50 inhaler 2 months after first opening the foil bag.

If your SALFLUMIX EASYHALER gets damp, you need to replace it with a new one.

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.

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.

Allergic reactions:

You may notice **your breathing suddenly gets worse** after using SALFLUMIX EASYHALER. You may be very wheezy and cough. You may also notice itching and swelling (usually of the face, lips, tongue, or throat). **If you get these effects or if they happen suddenly after using SALFLUMIX EASYHALER, tell your doctor straight away or go to Accident and Emergency at your nearest hospital.**

Common Side Effects

- sore, yellowish, raised patches in the mouth (thrush)
- soreness in the mouth, throat, or tongue
- hoarseness
- headache
- muscle cramps
- pains in joints
- increase in heart rate

Pneumonia (lung infection) has been reported commonly in patients with COPD. Tell your doctor if you notice any of the following symptoms:

- increase in sputum production
- change in sputum colour
- fever, chills
- increased cough and increased breathing problems.

Uncommon Side Effects

- skin rash
- shortness of breath
- sweating, trembling, feeling nervous or anxious
- bruising
- eye problems (e.g. cataract, glaucoma)
- sleep disturbances

Rare Side Effects

- behavioural changes, including unusual activity and irritability
- rounded face
- slowing of growth in children and adolescents
- soreness in the oesophagus
- irregular heartbeat

The above list includes very serious side effects that may need urgent medical attention or hospitalisation.

Some side effects can only be found when your doctor does tests from time to time to check your progress, for example:

- increases in blood sugar (glucose) levels
- changes in blood pressure
- loss of bone density
- reduced potassium levels in the blood
- changes in the function of the adrenal glands, which make the body's own steroids

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 SALFLUMIX EASYHALER contains

Active ingredients (main ingredients)	250 or 500 micrograms Fluticasone propionate and 50 micrograms Salmeterol (as salmeterol xinafoate)
Other ingredients (inactive ingredients)	Lactose monohydrate
Potential allergens	Lactose monohydrate Milk proteins

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

What SALFLUMIX EASYHALER looks like

SALFLUMIX EASYHALER is a dry powder inhaler device that contains a white to yellowish powder. Each inhaler is in a

sealed foil bag and packed in a cardboard box together with a protective cover. Each inhaler contains 60 doses.

SALFLUMIX EASYHALER 500/50 (AUST R 338158).

SALFLUMIX EASYHALER 250/50 AUST R 338157).

Who distributes SALFLUMIX EASYHALER

Orion Pharma (Aus) Pty Limited

Level 24, Tower 3

300 Barangaroo Avenue, Sydney, NSW 2000, Australia

Telephone: 1800 861 913

This leaflet was prepared in February 2024.