

FOSTAIR[®] 100/6 and 200/6

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 FOSTAIR?

FOSTAIR contains the active ingredients beclometasone dipropionate and formoterol fumarate dihydrate. FOSTAIR is used to provide relief and prevent symptoms such as shortness of breath, wheezing (whistling or rattling sound) and cough in adults (18 years or over) with chronic obstructive pulmonary disease (COPD) and asthma.

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

2. What should I know before I use FOSTAIR?

Do not use if you have ever had an allergic reaction to FOSTAIR 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, are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with FOSTAIR 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 FOSTAIR?

- Inhale FOSTAIR into the lungs through the mouth, in the morning and in the evening even if you feel well.
- Some people with asthma may also use FOSTAIR 100/6 as a reliever if asthma symptoms get worse.

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

5. What should I know while using FOSTAIR?

Things you should do	<ul style="list-style-type: none">• Always keep a fast-acting reliever or FOSTAIR 100/6 inhaler handy in case your breathing gets worse.• Seek medical help immediately if your COPD or asthma symptoms suddenly get worse just after using FOSTAIR.• Remind any doctor, dentist, or pharmacist you visit that you are using FOSTAIR.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the amount you use or use it for any other complaints without speaking to your doctor first.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how it affects you. Some people might experience side effects such as dizziness or blurred vision.
Looking after your medicine	<ul style="list-style-type: none">• Store the unused inhaler(s) in a refrigerator (2°C-8°C) until you are ready to use one. Do not freeze.• After first use, store the inhaler below 30°C for up to 2 months. Do not put the inhaler you are using back into the refrigerator.• Enter the date of first use on the removable label and stick it onto the inhaler.

For more information, see Section [5. What should I know while using FOSTAIR?](#) 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.

Common side effects may include: sore, yellowish, raised patches in the mouth (thrush); hoarse voice; red, sore, swollen, dry and/or irritated throat or tonsils and headache.

Serious side effects may include: allergic symptoms (such as rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body); worsening shortness of breath and wheezing; heart problems including angina (crushing chest pain that may spread to the arms, neck, shoulders or back) and lung infection (fever or chills, increased mucus production, change in mucus colour, increased cough).

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.

FOSTAIR[®] 100/6 and 200/6

Active ingredients: beclometasone dipropionate and formoterol fumarate dihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using FOSTAIR. **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 FOSTAIR.**

Where to find information in this leaflet:

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

1. Why am I using FOSTAIR?

FOSTAIR contains the active ingredients beclometasone dipropionate and formoterol fumarate dihydrate.

Beclometasone dipropionate belongs to a group of medicines called corticosteroids which works to reduce the swelling and irritation in your lungs.

Formoterol fumarate dihydrate is a long-acting bronchodilator which helps to open the airways wider and allowing you to breathe more easily.

FOSTAIR is used to provide relief and prevent symptoms such as shortness of breath, wheezing and cough in adults with Chronic Obstructive Pulmonary Disease (COPD) or asthma.

Chronic Obstructive airways disease (COPD)

COPD is a serious long-term disease where the airways become blocked and air sacs inside the lungs become damaged, leading to problems breathing.

FOSTAIR 100/6 is used every day for preventing COPD symptoms.

Asthma

Asthma is a serious, long-term disease where the muscles surrounding the airways become tight (bronchoconstriction) and swollen and irritated (inflammation). Symptoms such as shortness of breath, wheezing, chest tightness and cough can come and go.

FOSTAIR 100/6 and FOSTAIR 200/6 are both used every day for preventing asthma symptoms.

FOSTAIR 100/6 is also used as an asthma reliever as well as a preventer.

2. What should I know before I use FOSTAIR?

Warnings

Do not use FOSTAIR if:

- you are allergic to beclometasone dipropionate, 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.

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - heart or heart rhythm problems
 - high blood pressure or swollen, narrow, blocked or weakened blood vessels
 - chest infection, tuberculosis (TB), mouth or throat infection
 - thyroid problems
 - diabetes or high blood sugar (if you have diabetes it is important that your blood glucose levels are closely monitored in case they start to go up)
 - low blood potassium (your doctor may want you to have regular blood tests to keep an eye on your blood potassium levels)
 - liver or kidney disease
 - a tumour of the adrenal gland (phaeochromocytoma)
- 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.

Your doctor will talk to you about whether the benefits of having FOSTAIR outweigh any possible effects on your unborn baby.

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

Children and adolescents

Do not give this medicine to children and adolescents below the age of 18 years.

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 FOSTAIR and affect how it works. These include:

- medicines for treating high blood pressure and heart problems (such as digoxin, quinidine, disopyramide, procainamide)
- medicines to treat glaucoma (including eyedrops)
- medicines to treat migraines
- other medicines to treat COPD or asthma (such as theophylline, aminophylline or corticosteroids)
- medicines used to treat allergic reactions (antihistamines)
- medicines to treat depression or mental disorders such as monoamine oxidase inhibitors (phenelzine, isocarboxazid), tricyclic antidepressants (amitriptyline, imipramine) or phenothiazines
- medicines for HIV such as ritonavir, cobicistat
- L-dopa, used to treat Parkinson's Disease
- L-thyroxine, used to treat an underactive thyroid gland
- oxytocin, used to bring on (induce) labour
- procarbazine, used for treating certain cancers
- fluid or water tablets
- certain anaesthetics used during surgery
- alcohol or medicines containing alcohol
- disulfiram, used to help people avoid drinking alcohol
- metronidazole and furazolidone, antibiotics to treat infection in your body.

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

4. How do I use FOSTAIR?

How much to use

- FOSTAIR should be used regularly, in the morning and evening, to prevent COPD or asthma symptoms.
- Some people with asthma will also use FOSTAIR 100/6 as a reliever to treat sudden worsening of asthma symptoms. Your doctor will tell you the dose and how to use FOSTAIR to control your asthma.
- Follow the instructions provided and keep using FOSTAIR unless your doctor tells you to stop.

COPD - regular use

FOSTAIR 100/6: Two puffs in the morning and two puffs in the evening, continuously.

Asthma - regular use

FOSTAIR 100/6: One or two puffs in the morning and evening, up to four puffs in one day. You will usually start on the lowest amount first.

FOSTAIR 200/6: Two puffs in the morning and two puffs in the evening, up to four puffs in one day.

If changing from FOSTAIR 100/6 to FOSTAIR 200/6 your doctor will tell you to stop using 100/6 first.

Asthma - regular and reliever use

FOSTAIR 100/6 only: Have your regular puffs every day (one puff morning and evening), even if you don't have asthma symptoms.

If your asthma gets worse, have one puff, wait a few minutes and if it is no better have another puff. Don't have more than 6 reliever puffs on any single occasion (i.e. no more than a total of 8 puffs per day which includes your regular puffs). **If you need to do this for two days in a row, then see your doctor straight away.**

When to use FOSTAIR

Use FOSTAIR every day even when your COPD or asthma is not troubling you.

Your doctor may tell you to use a separate reliever inhaler or to use FOSTAIR 100/6 as a reliever to treat sudden worsening of your asthma symptoms.

If you feel that the medicine is not working or you are getting breathless or wheezy, talk to your doctor.

How to use the inhaler

You should inhale the medicine through your mouth, and this takes the medicine directly into your lungs.

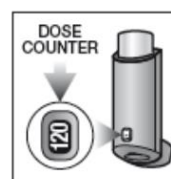
This medicine is contained in a pressurised canister enclosed in a plastic inhaler with a mouthpiece. Each inhaler contains 120 puffs (other presentations are not currently available).

There is a counter on the back of the inhaler, which corresponds to the number of puffs left in the container. Each time you press the pressurised canister, a puff of medicine is released, and the counter will count down by one. Take care not to drop the inhaler as this may cause the counter to count down.

Priming your inhaler

Before using the inhaler for the first time or if you have not used the inhaler for 14 days or more, you should prime your inhaler to make sure that it is working properly.

1. Remove the protective cap from the mouthpiece
2. Hold your inhaler upright with the mouthpiece at the bottom
3. Direct the mouthpiece away from yourself and firmly press the canister to release one puff
4. Check the dose counter. If you are testing your inhaler for the first time, the counter should read: **120**

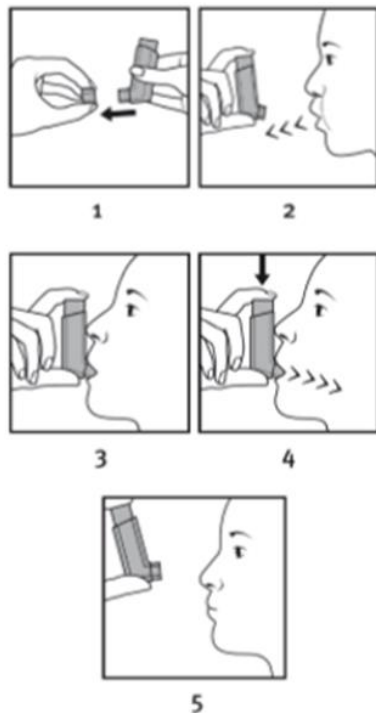


How to use your inhaler

Stand or sit up when inhaling.

Important: Do not perform steps 2 to 5 too quickly.

1. Remove the protective cap from the mouthpiece and check that the mouthpiece is clean and free from dust, dirt or any other foreign objects.
2. Breathe out as slowly and deeply as possible, in order to empty your lungs.
3. Hold the inhaler upright with the mouthpiece at the bottom and place the mouthpiece between your teeth without biting it. Then place your lips around the mouthpiece, with the tongue flat under it.
4. Breathe in slowly and deeply through your mouth to fill your lungs with air (this should take about 4-5 seconds). Just after starting to breathe in, press down firmly on the top of the canister to release one puff.
5. Hold your breath for as long as possible and, finally, remove the inhaler from your mouth and breathe out slowly. Do not breathe out into the inhaler.
6. Check that the dose counter has moved down by one.



If you need to take another puff, keep the inhaler in the vertical position for about half a minute, then repeat steps 2 to 5.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that FOSTAIR will not be getting into your lungs as it should. Take another puff, following the instructions starting again from step 2.

You may not feel a strong puff when you inhale it into the lungs due to the fine 'mist' released by the inhaler. Ask your doctor or pharmacist to check your technique to ensure you are using it correctly.

After use

Replace the protective cap.

To prevent a fungal infection in the mouth and throat, rinse your mouth or gargle with water without swallowing it or brush your teeth after each use of your inhaler.

When to get a new inhaler

You should get a replacement when the counter shows the number 20. Stop using the inhaler when the counter shows 0, as any medicine left in the inhaler may not be enough to give you a full puff.

If you find it difficult to use the inhaler

If you have a weak grip, it may be easier to hold the inhaler with both hands. Hold the upper part of the inhaler with both index fingers and its lower part with both thumbs.

If you find it difficult to use the inhaler while starting to breathe in, you may use a suitable spacer device. Ask your doctor or pharmacist about this device.

It is important that you read the package leaflet which is supplied with your spacer device and that you carefully follow the instructions on how to use the spacer device and how to clean it.

Cleaning the FOSTAIR inhaler

You should clean your inhaler once a week.

1. Do not remove the canister from the inhaler and do not use water or other liquids to clean your inhaler.
2. Remove the protective cap from the mouthpiece by pulling it away from your inhaler.
3. Wipe inside and outside of the mouthpiece and the inhaler with a clean, dry cloth or tissue.
4. Replace the mouthpiece cap.

If you forget to use FOSTAIR

FOSTAIR should be used regularly at the same times each day. If you miss your dose at the usual time, use it as soon as you remember.

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

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

If you use too much FOSTAIR

If you think that you have used too much FOSTAIR, 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 FOSTAIR?

Things you should do

- Keep using FOSTAIR every day, even if your COPD or asthma is under control
- Clean your inhaler once a week using a dry cloth or tissue
- Always keep a separate fast-acting reliever or your FOSTAIR 100/6 inhaler handy in case your breathing gets worse
- If you have asthma, make sure you have an up-to-date Asthma Action Plan so you know what to do if you have a flare-up or asthma attack.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor will test your lung function, change the dose if needed and check any effects on your general health.

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.

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

Call your doctor straight away if:

- you become pregnant while taking this medicine
- your breathing gets worse, this may include shortness of breath or wheezing straight after using FOSTAIR. Stop using FOSTAIR and use a fast-acting reliever inhaler.
- you get blurred vision or other problems with your eyesight.

Things you should not do

- Do not stop using your medicine or change the dosage without checking with your doctor.
- Do not use FOSTAIR to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same symptoms as you.

Driving or using machines

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

FOSTAIR may cause dizziness or blurred vision in some people.

Things to be careful of

If you take higher doses of inhaled corticosteroids over long periods, you may need a higher dose of corticosteroids in stressful situations such as being taken to hospital after an accident, having a serious injury or before an operation. Your doctor will decide whether you need to increase your dose of corticosteroids and may prescribe some steroid tablets or a steroid injection.

FOSTAIR contains alcohol

The amount of alcohol in two puffs of this medicine is equivalent to less than 1 mL of wine or beer. The small amount of alcohol in this medicine will not have any noticeable effects, however talk to your doctor if you have been told to avoid alcohol for any reason.

Looking after your medicine

- Store the unused inhaler(s) in a refrigerator (2°C-8°C) until you are ready to use one. Do not freeze.
- Before using for the first time, take one inhaler out of the refrigerator for a few minutes to allow the solution to warm up.
- After first use, store the inhaler below 30°C for up to 2 months.
- Enter the date of first use on the removable label and stick it onto the inhaler. **Do not put the inhaler back into the refrigerator.**

Keep the inhaler that you are using 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 windowsills.

Keep it where young children cannot reach it.

The canister contains a pressurised liquid. Do not puncture, expose to heat (i.e. temperatures higher than 50°C) or incinerate.

When to discard your medicine

- If your doctor tells you to stop using this medicine
- Two months after first using the inhaler
- When you have used all of the puffs and the dose counter shows zero (0)
- If it is damaged or the expiry date has passed.

Getting rid of any unwanted medicine

Take it to any pharmacy where it will be disposed of safely.

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>Circulation:</p> <ul style="list-style-type: none"> increased blood flow to a part of the body or flushing increased or decreased blood pressure <p>Digestive system:</p> <ul style="list-style-type: none"> indigestion feeling sick (nausea) loose stools (diarrhoea) severe diarrhoea and/or vomiting (gastroenteritis) <p>Ear, nose, throat and mouth:</p> <ul style="list-style-type: none"> red, sore, swollen, dry and/or irritated nose, throat or tonsils, with or without fever sore, yellowish, raised patches in the mouth or throat (thrush), other fungal infection of the mouth hoarse voice unpleasant or unusual taste sensation dry, swollen or sore mouth irritated tongue and mouth problems swallowing burning lips pressure or pain behind the eyes/nose (sinusitis) or ears (including hearing problems) runny or stuffy nose, sneezing <p>Eyes:</p> <ul style="list-style-type: none"> eye problems such as glaucoma or cataract blurred vision, problems seeing properly <p>General body:</p> <ul style="list-style-type: none"> swelling in the hands, ankles or feet <p>Hormones:</p> <ul style="list-style-type: none"> problem with your adrenal glands (Cushing's syndrome) which may include symptoms such as weight gain, rounded (moon-shaped) face and high blood pressure <p>Infections:</p> <ul style="list-style-type: none"> flu-like symptoms such as fever, chills, muscle aches, cough, blocked or runny nose, headaches and fatigue itching, burning and white discharge in the vagina (thrush, a fungal infection) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<p>Kidneys:</p> <ul style="list-style-type: none"> passing less urine than normal, coloured or foamy urine, feeling or being sick, swollen face, hands, feet and abdomen (may be a sign of kidney problems) <p>Lungs:</p> <ul style="list-style-type: none"> dry or chesty cough <p>Mental health:</p> <ul style="list-style-type: none"> feeling restless, hyperactive, anxious, depressed or aggressive sleeping problems changes in behaviour (mainly in children and adolescents) <p>Muscles and bones:</p> <ul style="list-style-type: none"> muscle spasms, muscle or bone pain decreased bone mineral density (leading to thinning bones) limited growth (children and adolescents) <p>Nervous system:</p> <ul style="list-style-type: none"> headache trembling, dizziness <p>Skin:</p> <ul style="list-style-type: none"> excessive sweating itchy red rash and/or small blisters on the skin bleeding or bruising more easily than normal, bleeding into the tissues <p>Tests requested by your doctor:</p> <ul style="list-style-type: none"> low levels of white blood cells lower blood cortisol low or high blood glucose levels higher C-reactive protein, free fatty acids, blood insulin, blood ketone body low potassium levels in the blood low blood platelet count 	
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Serious side effects

Serious side effects	What to do
<p>Heart:</p> <ul style="list-style-type: none"> thumping, fluttering, fast, slow or unusual heartbeat chest pain that may spread to arms, neck, shoulders or back (angina) <p>Hypersensitivity (allergic) reaction:</p> <ul style="list-style-type: none"> may include rash, itching or hives on the skin, skin redness, swollen face, lips, eyes, tongue or throat or other parts of the body 	<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
Lungs: <ul style="list-style-type: none"> • severe breathing problems and/or worsening of COPD/asthma straight after using FOSTAIR • fever or chills, increased phlegm/sputum production or a change in colour, increased cough or problems breathing (pneumonia) 	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.

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 FOSTAIR contains

Active ingredients (main ingredients)	<ul style="list-style-type: none"> • beclometasone dipropionate • formoterol fumarate dihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • dilute hydrochloric acid (may have been added to adjust the pH) • ethanol absolute (alcohol) • norflurane (a CFC-free propellant)

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

What FOSTAIR looks like

FOSTAIR is a colourless to yellowish liquid that comes in a pressurised aluminium canister within a plastic inhaler with a mouthpiece. You can see how many doses you have left in the window in the inhaler part.

The FOSTAIR 100/6 plastic inhaler is light purplish-red colour with a dark purplish-red cap. The pack contains a single inhaler with 120 puffs (AUST R 310360).

The FOSTAIR 200/6 plastic inhaler is light purplish-red colour with a dark green cap. The pack contains a single inhaler with 120 puffs (AUST R 373934).

Other presentations are not currently available.

Who supplies FOSTAIR

Chiesi Australia Pty Ltd
Suite 3, 22 Gillman Street,
Hawthorn East, VIC 3123.

Email: medinfo.au@chiesi.com

Website: www.chiesi.com.au

This leaflet was prepared in September 2024.