

FOSTAIR® 100/6 and 200/6

Beclometasone dipropionate 100 or 200 micrograms and formoterol (eformoterol) fumarate dihydrate 6 micrograms pressurised inhalation solution

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about FOSTAIR.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What FOSTAIR is used for

FOSTAIR is a pressurised metered dose inhaler containing two active substances which are inhaled through your mouth and delivered directly into your lungs.

The two active substances are beclometasone dipropionate and formoterol (eformoterol) fumarate dihydrate.

Beclometasone dipropionate is a corticosteroid, a medicine used to treat swelling and irritation in your lungs.

Formoterol (eformoterol) fumarate dihydrate is a long-acting bronchodilator, a medicine which relaxes the muscles in your airways

and helps you to breathe more easily.

Together these two active substances make breathing easier, by providing relief from symptoms such as shortness of breath, wheezing and cough in patients with asthma or Chronic Obstructive Pulmonary Diseases (COPD). They can also help to prevent the symptoms of asthma.

Asthma

FOSTAIR used for the treatment of asthma in adult patients in whom:

- asthma is not adequately controlled by using inhaled corticosteroids and “as needed” short-acting bronchodilators or
- asthma is responding well to treatment with both corticosteroids and long-acting bronchodilators.

COPD (FOSTAIR 100/6 only)

FOSTAIR 100/6 can also be used to treat the symptoms of severe COPD in adult patients. COPD is a long-term disease of the airways in the lungs which is primarily caused by cigarette smoking.

Ask your doctor if you have any questions about why FOSTAIR has been prescribed for you.

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use FOSTAIR

When you must not use it

Do not take FOSTAIR if you have an allergy to:

- any medicine containing beclometasone dipropionate or formoterol (eformoterol) fumarate dihydrate
- any of the ingredients listed at the end of this leaflet.

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.

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

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems (heart pain, pain in the chest, recent heart attack, heart failure, narrowing of the arteries around your heart, valvular heart disease or any

- other known abnormalities or conditions of your heart)
- narrowing of the arteries, have high blood pressure or an abnormal bulging of the blood vessel wall
- heart rhythm disorders such as increased or irregular heart rate, fast pulse rate, palpitations or abnormal heart trace (ECG)
- an overactive thyroid gland
- low blood levels of potassium
- disease of your liver or kidneys
- diabetes or high blood sugars
- a tumour of the adrenal gland
- tuberculosis (TB)
- viral or fungal chest infection.

FOSTAIR contains a small amount of alcohol. Talk to your doctor if you have been told to avoid alcohol for any reason.

Tell your doctor if you are pregnant or plan to become pregnant, or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, speak with your doctor before you start using FOSTAIR.

Taking other medicines

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

Some medicines and FOSTAIR may interfere with each other. These include:

- medicines for HIV such as ritonavir, cobicistat
- medicines for high blood pressure, heart conditions and abnormal heart rhythms (such as quinidine, disopyramide, procainamide)
- medicines to treat glaucoma
- medicines to treat migraines
- other medicines to treat COPD or asthma (such as theophylline,

- aminophylline or corticosteroids)
- medicines used to treat allergic reactions such as antihistamines
- medicines to treat depression or mental disorders such as monoamine oxidase inhibitors (phenelzine and isocarboxazid), tricyclic antidepressants (amitriptyline and imipramine) or phenothiazines
- L-dopa, a medicine used to treat Parkinson's Disease
- L-thyroxine, a medicine used to treat an underactive thyroid gland
- oxytocin, used to bring on (induce) labour
- alcohol
- fluid or water tablets
- disulfiram, a medicine used to treat drinking problems
- metronidazole, an antibiotic to treat infection in your body
- anaesthetics used during surgery.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use FOSTAIR

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to use

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Asthma

FOSTAIR can be used in two different ways:

(a) use FOSTAIR 100/6 or FOSTAIR 200/6 every day to treat your asthma together with a separate “reliever” inhaler to treat sudden worsening of asthma symptoms, such as shortness of breath, wheezing and cough

(b) use FOSTAIR 100/6 every day to treat your asthma and also use FOSTAIR 100/6 to treat sudden worsening of your asthma symptoms, such as shortness of breath, wheezing and cough.

Your doctor will advise you on the dose and how to use FOSTAIR to control your asthma.

a) Using FOSTAIR together with a separate “reliever” to treat sudden worsening of asthma symptoms, such as shortness of breath, wheezing and cough

FOSTAIR 100/6

The recommended dose is one or two puffs twice daily. The maximum daily dose is 4 puffs.

FOSTAIR 200/6

The recommended dose is two puffs twice daily. The maximum daily dose is 4 puffs.

You will be told to stop using FOSTAIR 100/6 before starting on FOSTAIR 200/6.

Remember: You should always have your quick-acting “reliever” inhaler with you at all times to treat worsening symptoms of asthma or a sudden asthma attack.

If you are using more inhalations of your reliever than usual, tell your doctor as this may indicate worsening of your asthma.

b) Using FOSTAIR 100/6 every day to treat your asthma and also use FOSTAIR 100/6 to treat sudden worsening of your asthma symptoms, such as shortness of breath, wheezing and cough

FOSTAIR 100/6 only

The recommended dose is one puff twice daily.

You should also use FOSTAIR 100/6 as a “reliever” inhaler to treat sudden asthma symptoms.

If you get asthma symptoms, take one puff and wait a few minutes. If you do not feel better, take another puff. Do not take more than 6 reliever puffs on any single occasion.

The maximum daily dose of FOSTAIR 100/6 is 8 puffs.

If you feel you need more puffs each day to control your asthma symptoms, talk to your doctor. Your doctor may need to change your medicines.

COPD (FOSTAIR 100/6 only)

The recommended dose of FOSTAIR 100/6 is two puffs twice daily in the morning and two puffs in the evening.

How to use it

Testing your inhaler

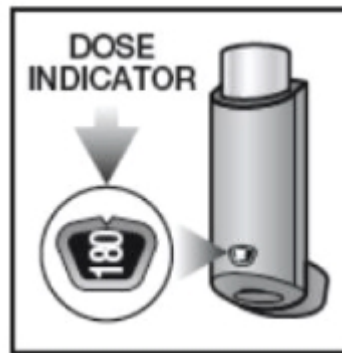
Before using the inhaler for the first time or if you have not used the inhaler for 14 days or more, you should test your inhaler to make sure that it is working properly.

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 depress the canister to release one puff
4. Check the dose counter. If you are testing your inhaler for the first time, the counter/indicator should read:

120 - when using the containing providing 120 puffs.



180 - when using the containing providing 180 puffs.



How to use your inhaler

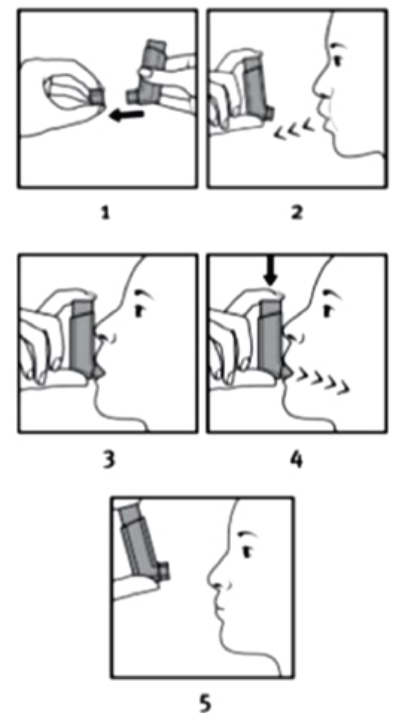
FOSTAIR is for inhalation use.

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

Whenever possible, stand or sit in an upright position 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 and dirt or any other foreign objects.
2. Breathe out as slowly and deeply as possible.
3. Hold the canister vertically with its body upwards and put your lips around the mouthpiece. Do not bite the mouthpiece.
4. Breathe in slowly and deeply through your mouth and, just after starting to breathe in press down firmly on the top of the inhaler 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 breath into the inhaler.



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 instruction starting again from step 2.

After use, close with the protective cap and check the dose counter.

To lower the risk of a fungal infection in the mouth and throat, rinse your mouth or gargle with water or brush your teeth each time you use your inhaler.

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

If you have weak hands, 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 operate 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 follow the instructions on how to use the spacer device and how to clean it, carefully.

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 cover.

When to use it

You should use FOSTAIR every day, even when your asthma or COPD 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 long to use it

Continue taking your medicine for as long as your doctor tells you.

Do not stop using FOSTAIR or lower the dose, even if you are feeling better or have no symptoms.

It is important to use FOSTAIR every day as directed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to use FOSTAIR

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 take a double to make up for the dose you have 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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken or been given too much FOSTAIR.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you use more FOSTAIR than you should, side effects may occur (see “Side Effects”).

While you are using FOSTAIR

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FOSTAIR.

Contact your doctor if you experience blurred vision or other visual disturbances.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all your doctor's appointments so that your progress can be checked.

Stop taking FOSTAIR, use your quick-acting “reliever” inhaler and seek medical help immediately if your breathing gets worse, this may include short of breath or start wheezing (breathing with an audible whistling sound) straight after using FOSTAIR.

Things you must not do

Do not take 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 condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

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

FOSTAIR contains 9 mg of alcohol (ethanol) in each actuation which is equivalent to 0.25 mg/kg per dose of two actuations. The amount in two actuations of this medicines 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking FOSTAIR.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sore, raised patches in the mouth, throat or oesophagus (food pipe) caused by a fungal infection (oral thrush). Rinsing your mouth out with water immediately after using the inhaler may prevent this side effect.
- sore, dry or irritated throat
- hoarseness of the voice
- headache
- flu-like symptoms
- runny or stuffy nose and sneezing
- feeling of tension or fullness in your sinuses
- cough
- inflammation of the ear
- skin rash, hives, itchy skin
- increased sweating, flushing of the skin
- fungal infection of the vagina with itching, burning and white discharge (thrush)
- diarrhoea, indigestion, upset stomach, nausea
- abnormal or impaired sense of taste, burning of the lips, dry mouth, swallowing difficulties
- muscle cramps or pain
- swelling of the hands and feet
- bleeding or bruising more easily than normal, bleeding into the tissues
- trembling, restlessness
- dizziness

- painful, difficult or frequent urination (may be a sign of a kidney infection)
- irregular heartbeat, sensation of fast or missed heart beats, palpitations.

The above list includes less serious side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- symptoms of a lung infection such as fever or chills, increased mucus production, change in mucus colour, or increased cough or increased breathing difficulties
- severe chills, sore throat or mouth ulcers.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- worsening shortness of breath and wheezing immediately after using FOSTAIR
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
- blurred vision
- crushing chest pain often spreading to the arms or neck and sometimes to the shoulders and back (angina).

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

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

Other side effects not listed above may occur in some patients. Some of these side effects (for example, changes in blood pressure, changes in blood levels of sugars, electrolytes, hormones, blood cells, cells to help your blood clot, fatty acids, ketones, or proteins in the blood) can only be found when your

doctor does tests from time to time to check your progress.

Using high-dose inhaled corticosteroids over a long time can cause other very rare side effects. FOSTAIR does not contain a high-dose of corticosteroids, however, your doctor will monitor you for other rare side effects such as:

- problems with how your adrenal glands work
- thinning of your bones
- increased pressure in your eyes (glaucoma)
- clouding of the lens of your eyes (cataracts)
- changes in behaviour such as sleeping problems, depression or feeling worried, restlessness, nervousness, over-excitement or irritability
- growth retardation or behavioural changes in children and adolescents.

After using FOSTAIR

Storage

Keep it where children cannot reach it.

If the inhaler has been exposed to severe cold, warm it with your hands for a few minutes before using. Never warm it by artificial means.

Warning: The canister contains a pressurised liquid. Do not expose the canister to temperatures higher than 50°C. Do not pierce the canister.

After opening:

120 or 180 puff inhalers:
Store below 30°C for a maximum of 2 months. Your pharmacist will enter the dispensing date on a label affixed to the inhaler.

From a multipack:
Store the unused inhaler(s) in a refrigerator (2°C-8°C) until you are ready to use. Do Not Freeze.

Before use, take one inhaler out of the refrigerator for some minutes to allow for the solution to warm up. After first use, store the inhaler below 30°C for a maximum of 2 months. Enter the date of first use on the removable label and affix to the inhaler. **Do not put the inhaler back into the refrigerator.**

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

FOSTAIR is a pressurised solution.

FOSTAIR comes in an aluminium canister with a metering valve, fitted in a polypropylene plastic inhaler with a plastic protective cap and dose counter.

For FOSTAIR 100/6 the plastic inhaler is light purplish-red with a dark purplish-red cap.

For FOSTAIR 200/6 the plastic inhaler is light purplish-red with a dark green cap.

FOSTAIR 100/6

Pack of 1 container with either 120 or 180 puffs.

Multipack containing 240 puffs (2 containers of 120 puffs each)

FOSTAIR 200/6

Pack of 1 container with 120 puffs.

Multipack containing 240 puffs (2 containers of 120 puffs each).

Not all pack sizes may be marketed.

Ingredients

The active ingredients of FOSTAIR are beclometasone dipropionate and formoterol fumarate dihydrate.

FOSTAIR 100/6:

Each metered dose (the dose leaving the mouthpiece) contains

100 micrograms of beclometasone dipropionate, 6 micrograms of formoterol (eformoterol) fumarate dihydrate.

FOSTAIR 200/6:

Each metered dose (the dose leaving the mouthpiece) contains 200 micrograms of beclometasone dipropionate, 6 micrograms of formoterol (eformoterol) fumarate dihydrate.

The other ingredients are:

- ethanol absolute (alcohol)
- hydrochloric acid
- norflurane as the propellant.

Supplier

FOSTAIR is supplied by:

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

Email:

medicalaffairs.au@chiesi.com

W: www.chiesi.com.au

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FOSTAIR 100/6: AUST R 310360

FOSTAIR 200/6: AUST R 373934