

FOSTER PRESSURISED INHALATION SOLUTION

Beclometasone dipropionate / Formoterol Fumarate Dihydrate (100/6 mcg/dose)

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What Foster is used for

Foster is indicated in the regular treatment of:

Asthma

- asthma not adequately controlled with inhaled corticosteroids and “as needed” rapid-acting β_2 -agonists or
- asthma already controlled on both inhaled corticosteroids and long-acting β_2 -agonists.

COPD

-Foster can also be used to treat the symptoms of severe chronic obstructive pulmonary disease (COPD) in adults. COPD is a long term disease of the airways in the lungs which is primarily caused by cigarette smoking.

How Foster works

Foster is a pressurised inhalation solution containing beclometasone dipropionate, a glucocorticoid with anti-inflammatory action reducing the swelling and irritation in the walls of the small air passage in the lungs, and formoterol fumarate, a selective β_2 -adrenergic agonist that produces relaxation of bronchial smooth muscle in reversible airway obstruction. The combination of these active substances make breathing easier, by providing relief from symptoms such as shortness of breath, wheezing and cough in

asthma and also help to prevent asthma worsening.

Before you use Foster

- When you must not use it:

-If you are allergic or think you are allergic to one or other of the active ingredients of Foster, or if you are allergic to other medicines or inhalers used to treat asthma or to any of the other ingredients of Foster, contact your doctor for advice.

Pregnancy and breast feeding

There are no clinical data on the use of Foster during pregnancy.

Foster should not be used if you are pregnant, think that you might be pregnant or are planning to become pregnant, or if you are breast-feeding, unless you are advised to do so by your doctor.

Before you start to use it

-Take special care with Foster and always tell your doctor before using it if you have any of the following conditions:

-any heart problems, such as pain in the chest, recent heart attack, heart failure, narrowing of the arteries around your heart, heart valve disease or any other known heart defects or condition where the heart muscle is abnormal.

-Arteriosclerosis (hardening and thickening of the walls of the blood vessels), high blood pressure, an abnormal bulging of the blood vessel wall, heart rhythm disorders such as increased or irregular heart rate, fast pulse rate or palpitations, abnormal heart trace.

-Overactive thyroid gland, low potassium blood levels, any disease of your liver or kidneys, diabetes (inhaling high doses of formoterol, your blood glucose may increase and therefore you may need to have some additional blood tests to check your

blood sugar when you start using this inhaler and from time to time during treatment).

-Adrenal gland tumour.

-You are due to have an anaesthetic.

Depending on the type of anaesthetic, it may be necessary to stop taking Foster at least 12 hours before the anaesthesia.

-You are being, or have ever been, treated for tuberculosis or if you have a known viral or fungal infection of your chest.

-You must avoid alcohol for any reason or had any medical problems, any allergies or if you are not sure as to whether you can use Foster.

Treatment with formoterol can cause a reduction in your serum potassium level.

If you have severe asthma, you should take special care.

This is because a lack of oxygen in the blood and some other treatments taken together with Foster like diuretics/ ‘water-tablets’ or other medicines for asthma can cause a reduction in blood potassium levels. For this reason your doctor may wish to measure the potassium levels in your blood periodically.

If you take higher doses of inhaled corticosteroids over long periods,

you may have more of a need for corticosteroids in situations of stress. In this case, your doctor will decide whether you may need to increase your dose of systemic corticosteroids. Should you need to go to the hospital, remember to take all of your medicines and inhalers with you including Foster and any medicines or tablets bought without a prescription, in their original package, if possible.

Taking other medicines

Before starting treatment, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any other inhalers and treatments obtained without prescription.

Do not use beta blockers with this medicine. If you need to use beta-blockers (including eye-drops), the effect of formoterol may be reduced or formoterol may not work at all. On the other hand, using medicines which work in the same way as formoterol may increase the effects of formoterol.

Using Foster together with:

- medicines for treating abnormal heart rhythms, allergic reactions, symptoms of depression or severe mental disorders such as monoamine oxidase inhibitors MAOI's, tricyclic antidepressants, phenothiazines can cause some changes in the electrocardiogram (to record the electrical activity of the heart) . They may also increase the risk of disturbances of heart rhythm.
- Medicines for treating Parkinson's Disease, an underactive thyroid gland, medicines which causes uterine contraction and alcohol can lower your heart's tolerance to formoterol.
- MAOIs, including medicines with similar properties like furazolidone and procarbazine, used to treat mental disorders, can cause a rise in blood pressure.
- Medicines for treating heart disease can cause a fall in your blood potassium level. This may increase the likelihood of abnormal heart rhythms.
- Other medicines used to treat asthma and diuretics may cause a fall in your potassium level.

How to use Foster

Foster is for inhalation use. Foster should be inhaled via your mouth into your lungs.

How much to use

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of Foster. He/she will adjust your treatment to the lowest dose that best controls your

symptoms. **Under no circumstances** should you change the dose without first asking your doctor.

Asthma

Foster can be prescribed by your doctor in two different ways:
a) Use Foster 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 Foster every day to treat your asthma and use Foster to treat sudden worsening of your asthma symptoms, such as shortness of breath, wheezing and cough.

a) Using Foster together with a separate "reliever":

Adults 18 years and above:

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

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.

b) Using Foster as your only asthma inhaler:

Adults 18 years and above:

The recommended dose is one puff in the morning and one puff in the evening.

You should also use Foster 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 Foster "reliever" puffs per day.

The maximum daily dose using Foster as your only asthma inhaler is 8 puffs.

If you feel you need more puffs each day to control your asthma symptoms, contact your doctor to seek their advice. They may need to change your treatment.

Use in children and adolescents less than 18 years of age:

Children and adolescents aged less than 18 years must NOT take this medicine.

Chronic obstructive pulmonary disease (COPD)

Adults 18 years and above:

The recommended dose is two puffs in the morning and two puffs in the evening.

At-risk patients:

Older people do not need to have their dose adjusted. No information is available regarding the use of Foster in people with liver or kidney problems.

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.

Cleaning

Remove the cap from the mouthpiece once weekly and wipe the outside and inside of the mouthpiece with a dry cloth. Do not use water or other liquids.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue using Foster for as long as your doctor recommends.

If you forget to use Foster:

Take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the correct time. **Do not double the dose.**

If you use too much (overdose)

-Taking more formoterol than you should can cause nausea, vomiting, irregular heartbeat, disturbances of heart rhythm, electrocardiogram modifications, headache, trembling, feeling sleepy, too much acid in the blood, low blood potassium levels, high levels of glucose in the blood. Your doctor may wish to carry out some blood tests to check your blood potassium and blood glucose levels.
-Taking too much beclometasone dipropionate can lead short-term problems with your adrenal glands. This will get better within a few days; however, your doctor may need to check your serum cortisol levels.

Tell your doctor if you have any of these symptoms.

While you are using Foster

Things you must do

Instructions for use:

Before using the inhaler for the first time or if you have not used the inhaler for 14 days or more, release one puff into the air to make sure the inhaler is working properly.

Whenever possible, stand or sit in an upright position when inhaling.

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 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 breathe into the inhaler.

After use, close with the protective cap.

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.

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

If you see 'mist' coming from the top of the inhaler or the sides of your mouth you should start again from step 2.

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.

If you think the effect of Foster is too much or not enough, tell your doctor or pharmacist.

Things you must not do

Do not increase the dose.

If you feel that the medicine is not very effective, always talk to your doctor before increasing the dose.

Do not stop using Foster abruptly.

Things to be careful of

If your asthma gets worse:

If your symptoms get worse or if you are using your "reliever" inhaler more frequently, or if your "reliever" inhaler does not improve your symptoms, see your doctor immediately. Your asthma may be getting worse and your doctor may need to change your Foster dose or prescribe alternative treatment.

As with other inhaler treatments there is a risk of worsening shortness of breath and wheezing immediately after using Foster and this is known as **paradoxical bronchospasm**. If this occurs you should **STOP using Foster immediately** and use your quick-acting "reliever" inhaler straightaway to treat the symptoms of shortness of breath and wheezing. You should contact your doctor straightaway. Your doctor may start you on another course of treatment. You may be told that you should not use Foster again.

Side effects

Like all medicines, Foster can cause side effects.

Tell your doctor immediately if you experience any hypersensitivity reactions like skin allergies, skin itching, skin rash, reddening of the skin, swelling of the skin or mucous membranes especially of the eyes, face, lips and throat.

Common (less than 1 in 10 people):

Fungal infections (of the mouth and throat), headache, difficulty in speaking, sore throat.

Uncommon (less than 1 in 100 people);

Palpitations, unusual fast heart beat and disorders of heart rhythm, some changes in the electrocardiogram, flu symptoms, fungal infections of the vagina, inflammation of the sinuses,

inflammation of the mucous membrane inside the nose, inflammation of the ear, throat irritation, cough and productive cough, asthma attack.

Nausea, abnormal or impaired sense of taste, burning of the lips, dry mouth, swallowing difficulties, indigestion, upset stomach, diarrhoea. Pain in muscle and muscle cramps, reddening of the face, increased blood flow to some tissues in the body, excessive sweating, trembling, restlessness, dizziness, nettle rash or hives.

Alterations of some constituents of the blood: a fall in the number of white blood cells, increase in the number of blood platelets, a fall in the level of potassium in the blood, increase in blood sugar level, increase in the blood level of insulin, free fatty acid and ketones, irregular heartbeat.

Rare (less than 1 in 1,000 people)

Feeling chest tightness, missed heartbeat, increased or decrease in blood pressure, inflammation of the kidney, swelling of skin and mucous membrane persisting for several days.

Very rare (less than 1 in 10,000 people)

Shortness of breath, worsening of asthma, a fall in the number of blood platelets, swelling of the hands and feet.

Using high-dose inhaled corticosteroids over a long time can cause very rare cases of systemic effects: these include problems with how your adrenal glands work, decrease in bone mineral density, growth retardation in children and adolescents, increased pressure in your eyes, cataracts.

Unknown

Psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

This is not a complete list of side effects.

If you experience any of the above side effects, you should contact your doctor or pharmacist immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers - > Reporting)

Storage and disposal of Foster

Storage

Keep out of the reach and sight of children.

Do not use Foster beyond 2 months from the date you get the inhaler from your pharmacist and never use after the expiry date which is stated on the carton and label.

Do not store the inhaler above 30 °C. Warning: The canister contains a pressurised liquid. Do not expose the canister to temperatures higher than 50 °C. Do not pierce the canister.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

Foster is a pressurised solution contained in an aluminium canister with a metering valve, fitted in a polypropylene plastic actuator with a plastic protective cap.

Each pack contains one canister which provides 120 puffs.

Ingredients

Active ingredients: beclometasone dipropionate, formoterol fumarate dihydrate.

Inactive ingredients: ethanol anhydrous (7 mg per puff), hydrochloric acid, propellant: norflurane (HFA 134-a).

MAL number

MAL20112126A

Manufacturer

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Product Registration Holder

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