

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Foster® 100/6

Pressurised solution for inhalation

The active ingredients and their quantities:

Each actuation releases:

Beclometasone dipropionate anhydrous 100 mcg and Formoterol fumarate dihydrate 6 mcg.

Inactive ingredients: see section 6 in the leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

The medicine is not intended for use in children and adolescents below the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of asthma

Foster 100/6 is intended to treat asthma, where use of a combination product (inhaled corticosteroid and long acting beta-2-agonist) is appropriate:

- Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting beta-2-agonist, or
- Patients already adequately controlled by combined treatment with inhaled corticosteroids and long acting beta-2 agonist.

Treatment of Chronic Obstructive Pulmonary Disease – COPD

Foster 100/6 is intended for treatment of severe COPD symptoms in patients with a history of recurrent episodes, who suffer significant symptoms despite treatment with long-acting bronchodilators.

Therapeutic group:

Formoterol - beta agonist, bronchodilator.

Beclometasone - corticosteroid.

The two active substances in Foster 100/6 are beclometasone dipropionate and formoterol fumarate dihydrate.

Beclometasone dipropionate belongs to a group called corticosteroids (also referred to as steroids), which have an anti-inflammatory action, and reduce swelling and irritation in the lungs. Formoterol fumarate dihydrate belongs to a group called long-acting bronchodilators, which relax the muscles in airways and by doing this, widen the airways, making it easier to breathe.

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 COPD patients and help to prevent the symptoms of asthma.

COPD is a chronic disease of the airways in the lungs, primarily caused as a result of smoking cigarettes.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients of the medicine (see section 6 in this leaflet), or if you are sensitive to other medicines or inhalers used for the treatment of asthma. Refer to a doctor for advice.

Special warnings regarding use of the medicine

❗ Before using Foster 100/6, inform the doctor if:

- You have heart problems, such as angina (heart or chest pain), you recently had a heart attack (myocardial infarction), heart failure, narrowing of the arteries around your heart (coronary heart disease), valvular heart disease or any other known abnormalities of your heart, or if you have a condition known as hypertrophic obstructive cardiomyopathy (also known as HOCM, a condition where the heart muscle is abnormal).
- You have narrowing of the arteries (also known as arteriosclerosis), if you have high blood pressure or if you know that you have an aneurysm (an abnormal bulging of the blood vessel wall).
- You have disorders of heart rhythm, such as increased or irregular heart rate, a fast pulse rate or palpitations, or if you have been told that your heart trace is abnormal.
- You have an overactive thyroid gland.
- You have low blood levels of potassium.
- You have any disease of your liver or kidneys.
- You have diabetes (if you inhale high doses of formoterol, your blood sugar (glucose) level may increase and you may need to have some additional blood tests to check your blood sugar level when you start using this inhaler and from time to time during treatment).
- You have a tumour of the adrenal gland (phaeochromocytoma).
- You are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking Foster 100/6 at least 12 hours before the anaesthesia.
- You are being, or have ever been, treated for tuberculosis (TB) or if you have a known viral or fungal infection of your chest.
- You must avoid alcohol for any reason.

If any of the above apply to you, inform the doctor before commencing treatment with Foster 100/6.

If you have or had any medical problems or any allergies, or if you are not sure as to whether you can use Foster 100/6, refer to a doctor or pharmacist before using the inhaler.

- Treatment with a beta-2-agonist like the formoterol contained in Foster 100/6 can cause a sharp fall in your blood potassium levels (hypokalaemia).

If you have severe asthma, you should take special care. This is because a lack of oxygen in the blood and other treatments you may be taking together with Foster 100/6, such as medicines for treating heart disease or high blood pressure, known as diuretics, or other medicines used to treat asthma can make the fall in potassium level worse. For this reason, the doctor will measure the potassium levels in your blood from time to time.

If you take high dosages of inhaled steroids over long periods, you may need higher quantities of steroids in situations of stress. Stressful situations might include being taken to hospital after an accident, a serious injury or before an operation. In this case, the doctor treating you will decide whether you need to increase your dosage of steroids and may prescribe steroid tablets or a steroid injection.

- Should you need to go to the hospital, remember to take all of your medicines and inhalers with you, including Foster 100/6 and non-prescription medicines, in their original package, if possible.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents:

The medicine is not intended for use in children and adolescents under 18 years of age.

Other medicines and Foster 100/6

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines, other inhalers and nutritional supplements, inform the doctor or pharmacist.

❗ It is particularly important to inform the doctor or pharmacist if you are taking:

- Some medicines may increase the effects of Foster 100/6 and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- **Do not use beta blockers with this medicine.** Beta blockers such as atenolol, propranolol and sotalol are used to treat a number of conditions including high blood pressure and heart conditions such as abnormal heart rhythms and heart failure; timolol is used to treat glaucoma. If you need to use beta blockers (including eye drops), the effect of formoterol may be reduced or it may not have an effect at all. On the other hand, using other beta-adrenergic drugs (drugs which work in the same way as formoterol) may increase the effect of formoterol.

Using Foster 100/6 together with:

- Medicines for treating abnormal heart rhythms (quinidine, disopyramide, procainamide), medicines used to treat allergic reactions (antihistamines), medicines for treating symptoms of depression or mental disorders, such as monoamine oxidase inhibitors (for example, phenelzine and isocarboxazid), tricyclic antidepressants (for example, amitriptyline and imipramine), and phenothiazines can cause some changes in the electrocardiogram (ECG, heart trace). They may also increase the risk of disturbances of heart rhythm (ventricular arrhythmias).
- Medicines for treating Parkinson's disease (L-dopa), medicines to treat an underactive thyroid gland (L-thyroxine), medicines containing oxytocin (which causes uterine contraction) and alcohol can lower your heart's tolerance to beta-2-agonists, such as formoterol.
- Monoamine oxidase inhibitors (MAOIs), including drugs with similar properties, like furazolidone and procarbazine, used to treat mental disorders, can cause a rise in blood pressure.
- Medicines for treating heart disease (digoxin) can cause a fall in blood potassium levels. This may increase the risk of abnormal heart rhythms.
- Other medicines used to treat asthma (theophylline, aminophylline or steroids) and diuretics may cause a fall in blood potassium levels.
- Different types of anaesthetics can increase the risk of abnormal heart rhythms.

❗ **Pregnancy, breast-feeding and fertility:** There are no clinical data on the use of Foster 100/6 during pregnancy. This medicine should not be used if you are pregnant or breast-feeding, think that you might be pregnant or are planning to become pregnant, unless you are advised otherwise by your doctor.

❗ **Driving and using machines:** It is unlikely that this medicine will affect your ability to drive and use machines. However if you experience side effects such as dizziness and/or trembling, your ability to drive or operate machinery may be affected.

❗ **Important information about some of the ingredients of the medicine:** Foster 100/6 contains a small amount of alcohol. Every actuation (puff) from your inhaler contains 7 mg of ethanol.

3. HOW SHOULD YOU USE THE MEDICINE?

- Foster 100/6 is intended for inhalation only.
- Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.
- **The dosage and treatment regimen will be determined by the doctor only.**

Treatment of asthma:

The doctor will perform regular check-ups to make sure you are taking the optimal dose of Foster 100/6. The doctor will prescribe the lowest dosage that best controls your symptoms.

Foster 100/6 can be prescribed by your doctor for asthma in two different ways:

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

a) Using Foster 100/6 together with a separate "reliever" inhaler:

Adults and the elderly: The usual dosage is one to 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 100/6 as your only asthma inhaler:

Adults and the elderly: The usual dosage is one puff in the morning and one puff in the evening, as a maintenance therapy, and in addition, use of Foster 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 per day.

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

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

Children and adolescents under 18 years of age: This medicine is not intended for use in children and adolescents below the age of 18.

Treatment for Chronic Obstructive Pulmonary Disease (COPD)

Adults and the elderly: the usual dosage is two puffs in the morning and two puffs in the evening.

At-risk patients: Older people do not need to have their dosage adjusted. No information is available regarding the use of Foster 100/6 in people with liver or kidney problems.

The doctor will advise you on the exact dosage of Foster 100/6 you should take for your asthma.

Foster 100/6 contains a combination of active ingredients, and therefore you might receive a dose of beclometasone dipropionate which is lower than you received in the past with other inhalers.

Do not exceed the recommended dose.

If you feel that the medicine is not effective enough, refer to your doctor before increasing the dose.

If you took a higher dosage of Foster 100/6 than you should:

- Taking a higher formoterol dosage than recommended might cause the following effects: feeling sick, vomiting, heart racing, palpitations, disturbances of heart rhythm, certain changes in the electrocardiogram (ECG, heart trace), 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 blood tests to check your blood potassium and blood glucose levels.

- Taking too much beclometasone dipropionate can lead to short-term problems with your adrenal gland. This condition will improve 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.

If you took an overdose or if a child accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of this medicine with you.

If you forgot to take this medicine at the scheduled time, take a dose 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 stop using this medicine: Do not lower the dose or stop using the medication, unless the doctor has instructed you to do so. Adhere to the treatment regimen recommended by the doctor. Even if you're feeling better, do not stop taking this medicine or lower the dosage without consulting the doctor. It is important for you to use the medicine regularly even though you may have no symptoms.

If your breathing gets worse:

If you develop **worsening shortness of breath or wheezing** (breathing with an audible whistling sound), straight after inhaling the medicine, stop using the Foster 100/6 inhaler immediately, use your quick-acting "reliever" inhaler straightaway and contact your doctor straightaway. The doctor will assess your symptoms and may start you on a different course of treatment, if necessary. See also section 4 Side Effects in this leaflet.

If your asthma gets worse:

- If your symptoms get worse or are difficult to control (e.g., if you are using a separate "reliever" inhaler or Foster 100/6 as a reliever inhaler more frequently for relief of a sudden worsening of your asthma symptoms) or if your "reliever" inhaler or Foster 100/6 does not help improve your symptoms, refer to your doctor immediately.

Your asthma may be getting worse and your doctor may need to change your dosage of Foster 100/6 or prescribe alternative treatment.

Method of administration

This medicine is contained in a pressurized canister in a plastic casing with a mouthpiece.

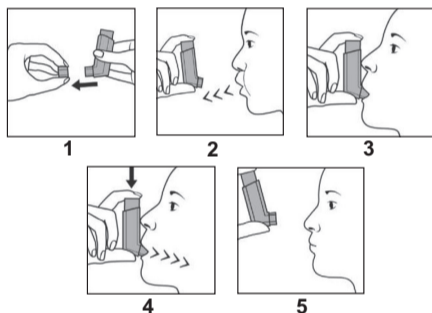
Testing your inhaler

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.

- Remove the protective cap from the mouthpiece.
- Hold your inhaler upright with the mouthpiece at the bottom.
- Direct the mouthpiece away from yourself and firmly depress the canister to release one puff.

How to use your inhaler

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 object.
2. Breathe out as slowly and deeply as possible.
3. Hold the canister vertically with its body upwards and put the mouthpiece in your mouth 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 breathe 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.

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

After use, cover the mouthpiece with the protective cap.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that Foster 100/6 will not be getting into your lungs as it should. Take another puff, following the instruction starting again from step 2.

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.

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

If you think the effect of Foster 100/6 is too strong or not effective enough, inform your doctor or pharmacist.

If you find it difficult to operate the inhaler while starting to breathe in, you may use the Aero-Chamber Plus™ spacer device. Ask the doctor or pharmacist about this spacer.

It is important that you read the package leaflet which is supplied with the Aero-Chamber Plus™ spacer device and that you carefully follow the instructions on how to use and clean the device.

Cleaning:

You should clean your inhaler once a week. When cleaning, do not remove the canister from the actuator and do not use water or other liquids to clean your inhaler.

To clean your inhaler:

1. Remove the protective cap from the mouthpiece by pulling it away from your inhaler.
2. Wipe inside and outside of the mouthpiece and the actuator with a clean, dry cloth or tissue.
3. Replace the mouthpiece cover.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Foster 100/6 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

As with other inhaler treatments, there is a risk of worsening shortness of breath and wheezing immediately after using Foster 100/6. This condition is known as **paradoxical bronchospasm**. If this occurs, **you should stop using Foster 100/6 immediately** and use your "reliever" inhaler straightaway to treat the symptoms of shortness of breath and wheezing. Contact your doctor straightaway.

You must refer to a doctor immediately if you experience reactions of hypersensitivity such as skin allergy, skin itching, rash, erythema (redness of the skin), swelling of the skin or mucous tissues, especially around the eyes, face, lips and throat.

Additional side effects are listed below according to frequency.

Common side effects (affects less than 1 in 10 people): Fungal infections (in the mouth and throat), headache, hoarseness, sore throat.

Pneumonia in COPD patients: tell your doctor if you have any of the following while taking Foster 100/6 as they could be symptoms of a lung infection:

- Fever or chills.
- Increased mucus production, change in mucus color.
- Increased cough or increased breathing difficulties.

Uncommon side effects (affects less than 1 in 100 people): Palpitations, unusual fast heartbeat and disorders of heart rhythm, changes in the electrocardiogram (ECG), flu symptoms, fungal infections of the vagina, inflammation of the sinuses, rhinitis, inflammation of the ear, throat irritation, cough and productive cough (a cough which releases phlegm), asthma attack.

Nausea, impaired or abnormal sense of taste, burning of the lips, dry mouth, swallowing difficulties, indigestion, upset stomach, diarrhea.

Pain in muscle and muscle cramps, reddening of the face, increased blood flow to some tissues in the body, excessive sweating, trembling, restlessness, dizziness, hives or nettle rash. Alterations of some constituents of the blood: 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, an increase in blood sugar levels, an increase in the blood level of insulin, free fatty acids and ketones.

The following side effects were reported with a frequency of "uncommon side effects" among patients with chronic obstructive pulmonary disease (COPD):

- Decrease in blood cortisol levels: caused as a result of the effect of corticosteroids on the adrenal gland.
- Irregular heartbeat.

Rare side effects (affect less than 1 in 1,000 people): Chest tightness, sensation of a missed heartbeat (caused by an early contraction of the ventricles of the heart), increase or decrease in blood pressure, inflammation of the kidney, swelling of skin and mucous membranes persisting for several days.

Very rare side effects: (affect 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 a high dosage of inhaled corticosteroids over a long time can cause systemic effects in very rare cases including: problems with how your adrenal glands work (adrenosuppression), decrease in bone density (thinning of the bones), growth retardation in children and adolescents, increased pressure in the eyes (glaucoma), cataracts.

Side effects with unknown frequency: Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These events are more likely to occur in children. Blurred vision.

If one of the side effects appears or worsens, or if you suffer from side effects that were not mentioned in the leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health through link "reporting side effects due to drug treatment" located in the home page of the Ministry of Health website (www.health.gov.it) which refers to online form, or by entering the following link: <https://sideeffects.health.gov.it>

Additionally, you may also report to Kamada LTD by email: pharmacovigilance@kamada.com

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

For the pharmacist (prior to dispensing to a patient):

At the pharmacy store in a refrigerator (at temperature of 2°C-8°C) for a maximum of 18 months.

Pharmacist: Ensure that there is a period of at least 3 months between the date of dispensing and the expiry date. Write the dispensing date to the patient on the package.

For the patient (after dispensing):

Once you receive the medicine from the pharmacist, store it at room temperature (below 25°C) for a maximum of 3 months.

Do not use the medicine beyond 3 months from the date you receive the inhaler from the pharmacist and do not use after the expiry date (exp. date) that appears on the carton and label. The expiry date refers to the last day of that month.

In the event the inhaler was exposed to severe cold, warm it up with your hands for a few minutes before use. Do not warm it up by artificial means.

Warning: The canister contains pressurized liquid. Do not expose the canister to temperatures above 50°C. Do not pierce the canister. The medicine should not be disposed via waste water or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, this medicine also contains: Norflurane (HFA 134-a), Ethanol anhydrous, Hydrochloric acid 1M.
- What does the medicine look like and the contents of the pack: Foster 100/6 is a pressurized solution contained in an aluminum canister with a metering valve, fitted in a polypropylene plastic actuator with a plastic protective cap. Each pack contains one canister which provides 120 actuations (puffs).
- License holder: Kamada Ltd., Beit Kama.
- Manufacturer: Chiesi Farmaceutici S.p.A., Parma, Italy.
- Revised in July 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1507333783.