

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

The medicine is dispensed with a doctor's prescription only

# Foster® 200/6

## Pressurised solution for inhalation

The active ingredients and their quantities:

Each actuation releases:

Beclometasone dipropionate 200 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?

Foster 200/6 is intended to treat asthma in adults, 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.

### Therapeutic group:

Foster 200/6 is a pressurised inhalation solution containing two active substances which are inhaled through your mouth and delivered directly into your lungs.

The two active substances in Foster 200/6 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 beta agonists, which are long-acting bronchodilators that relax the muscles in airways and by doing this, making it easier to breathe. These two active substances make breathing easier. They also help to prevent asthma symptoms such as shortness of breath, wheezing and coughing.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients (beclometasone dipropionate or formoterol fumarate dihydrate) or to any of the other ingredients of this medicine (listed in section 6).

#### Special warnings regarding use of the medicine

##### Before using Foster 200/6, inform the doctor if:

- You have heart problems, such as angina (heart pain, pain in the chest), heart failure, narrowing of the arteries, valvular heart disease or any other known abnormalities of your heart.
- You have a 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 (ECG) 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) may increase. When you start using Foster 200/6 and from time to time during treatment you may need to have some additional blood tests to check your blood sugar).
- 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 200/6 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 you have or had any medical problems or allergies, or if you are not sure as to whether you can use Foster 200/6, refer to a doctor or pharmacist before using the medicine.

- **If you take high dosages of inhaled corticosteroids over long periods,** you may need higher quantities of corticosteroids 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 corticosteroids 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 200/6 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.

#### Tests and monitoring:

- **When you start using Foster 200/6 and from time to time during treatment your doctor may wish to measure your blood sugar.**
- **When using Foster 200/6 your doctor may wish to measure the potassium levels in your blood from time to time especially if your asthma is severe.** Like many bronchodilators Foster 200/6 can cause a sharp fall in your serum potassium level (hypokalaemia). This is because a lack of oxygen in the blood combined with some other treatments you may be taking together with foster 200/6 can make the fall in potassium level worse.

#### Drug Interactions:

**If you are taking, or have recently taken, other medicines, including non-prescription medicines, and nutritional supplements, inform the doctor or pharmacist.** Particularly if you are taking:

- Some medicines may increase the effects of Foster 200/6 and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- Beta-blocker medicines. Beta blockers are medicines used to treat many conditions including heart problems, high blood pressure and glaucoma (increased pressure in the eyes). If you need to use beta blockers including eye drops, the effect of formoterol may be reduced or formoterol may not work at all.
- Beta adrenergic drugs (drugs which work in similar way as formoterol) may increase the effects of formoterol.
- 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 monoaminoxidase inhibitors (for example, phenelzine and isocarboxazid), tricyclic antidepressant medicines (for example, amitriptyline and imipramine), and phenothiazines.
- Medicines for treating Parkinson's disease (L-dopa).
- Medicines to treat an underactive thyroid gland (L-thyroxine).
- Medicines containing oxytocin (which causes uterine contraction).
- Medicines for treating mental disorders, such as monoaminoxidase inhibitors (MAOIs), including drugs with similar properties, like furazolidone and procarbazine.
- Medicines for treating heart disease (digoxin).
- Other medicines used to treat asthma (theophylline, aminophylline or steroids).
- Diuretics (water tablets).

Also tell your doctor if you are going to have a general anaesthetic for an operation or for dental work.

#### Pregnancy, breast-feeding and fertility:

There are no clinical data on the use of Foster 200/6 during pregnancy. Foster 200/6 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.

#### Driving and using machines:

It is unlikely that this medicine will affect your ability to drive and use machines.

#### Important information about some of the ingredients of the medicine:

Foster 200/6 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 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.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of Foster 200/6.

The doctor will perform regular check-ups to make sure you are taking the optimal dose of Foster 200/6. The doctor will prescribe the lowest dosage that best controls your symptoms. The dosage and treatment regimen will be determined by the doctor only. The usual dose is:

**Adults and the elderly:** The recommended dose is two actuations (puffs) twice daily. The maximum daily dose is 4 actuations (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.**

**At-risk patients:** There is no need for dose adjustment if you are older. No information is available regarding the use of Foster 200/6 in people with liver or kidney problems.

**Use in children and adolescents less than 18 years of age:** This medicine must not be used in children and adolescents aged less than 18 years old.

**Foster 200/6 is effective for the treatment of asthma in a dose of beclometasone dipropionate which may be lower than that of some other inhalers containing this substance. If you have been using a different inhaler containing beclometasone dipropionate previously, your doctor will advise you on the exact dose of Foster 200/6 you should take for your asthma.**

#### 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 your asthma gets worse:

If your symptoms get worse or are difficult to control (e.g. if you are using a separate "reliever" inhaler more frequently) or if your "reliever" inhaler does not improve your symptoms, refer to your doctor immediately. Your asthma may be getting worse and your doctor may need to change your dose of Foster 200/6 or prescribe alternative treatment.

#### Method of administration:

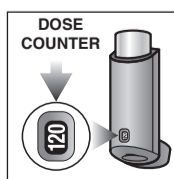
##### Foster 200/6 is intended for inhalation only.

This medicine is contained in a pressurized canister in a plastic casing with a mouthpiece. There is a counter on the back of the inhaler, which tells you how many doses are left. Each time you press the 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.

#### 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.
- Check the dose counter. If you are testing your inhaler for the first time, the counter should read 120.

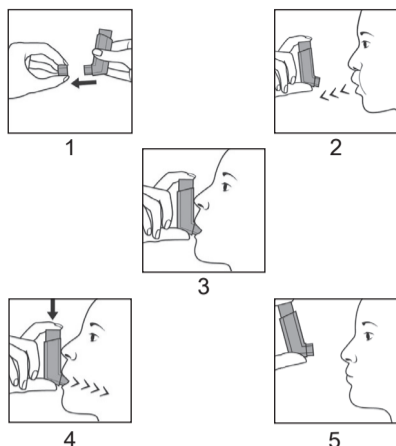


### How to use your inhaler:

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

Before you start inhaling, check the dose counter: any number between "1" and "120" shows that there are doses left.

If the dose counter shows "0", there are no doses left – dispose of your inhaler and get a new one.



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 the mouthpiece in your mouth, with your lips closed 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 actuation (puff). 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.
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 and check the dose counter.

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.

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

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that Foster 200/6 will not be getting into your lungs as it should. Take another puff, following the instruction starting again from step 2.

If you think the effect of Foster 200/6 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 device.

It is important that you read the package leaflet which is supplied with the AeroChamber 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.

### If you accidentally took a higher dosage:

- taking more formoterol than you should can have the following effects: feeling sick, being sick, 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 some 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 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.

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

**If you forget to use Foster 200/6** at the required time, 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 take a double dose to make up for a forgotten dose.**

Adhere to the treatment regimen recommended by your doctor.

**If you stop using the medicine:** even if you are feeling better, do not stop taking the medicine or lower the dose. If you want to do this, talk to your doctor. It is very important for you to use the medicine regularly even though you may have no symptoms.

**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 200/6 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 200/6; this condition is known as **paradoxical bronchospasm**. If this occurs, **you should STOP using Foster 200/6 immediately** and use your quick-acting "reliever" inhaler straightaway to treat the symptoms of shortness of breath and wheezing. Contact your doctor immediately.

**You must refer to a doctor immediately** if you experience **hypersensitivity reactions** like skin allergies, itching, rash, reddening of the skin, swelling of the skin or mucous tissues especially of eyes, face, lips and throat.

Additional side effects are listed below according to frequency.

**Common side effects** (appears in up to 1 in 10 people): Fungal infections (in the mouth and throat), headache, hoarseness, sore throat.

**Uncommon side effects** (appears in up to 1 in 100 people): Palpitations, unusual fast heartbeat and heart rhythm disorders, some changes in the electrocardiogram (ECG), increase in blood pressure, flu like symptoms, sinus inflammation, rhinitis, inflammation of the ear, throat irritation, cough and productive cough (a cough which releases phlegm), asthma attack, fungal infections of the vagina, nausea, abnormal or impaired 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 and throat, 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: fall in the number of white blood cells, increase in the number of blood platelets, fall in the level of potassium in the blood, increase in blood sugar levels, an increase in the blood level of insulin, free fatty acids and ketones.

The following side-effects have also been reported as "uncommon" among patients with chronic obstructive pulmonary disease (COPD):

- pneumonia; tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum colour, fever, increasing cough, increased breathing problems
- Reduction of the amount of cortisol in the blood; this is caused by the effect of corticosteroids on your adrenal gland
- Irregular heartbeat.

**Rare side effects** (appears in up to 1 in 1,000 people): Chest tightness, missed heartbeat (caused by premature contraction of the heart's ventricles), decrease in blood pressure, kidney inflammation, swelling of skin and mucous tissues persisting for several days.

**Very rare side effects:** (appears in up to 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 in very rare cases systemic effects.** These include: problems with how your adrenal glands work (adreno-suppression), 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 (the frequency is not established yet):** Sleeping problems, depression or anxiety, nervousness, feeling over-excited or irritable. These events are more likely to occur in children but the frequency is not known. Blurred vision.

**If one of the side-effects appear or worsen, or if you suffer from side-effects that were not mentioned in the leaflet, consult your doctor.**

### Reporting of side effects

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.il](http://www.health.gov.il)) which refers to online form, or by entering the following link:

<https://sideeffects.health.gov.il>

Additionally, you may also report to Kamada LTD by email:

[pharmacovigilance@kamada.com](mailto: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 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 patient on the package.

### For the patients (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) which is stated 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 1 M.
- What does the medicine look like and the contents of the pack: Foster 200/6 is a pressurized inhalation solution contained in an aluminum canister with a metering valve, fitted in a plastic actuator which incorporates a dose counter, with a plastic protective cap. Each pack contains one pressurized canister which provides 120 actuations (puffs).
- License holder: Kamada Ltd., Beit Kama.
- Manufacturer: Chiesi Farmaceutici S.p.A., Parma, Italy.
- Revised in February 2023 according to MOHs guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 164-70-35682