



PACKAGE LEAFLET: INFORMATION FOR THE USER

FOREBEC 100 mcg/6 mcg Capsules with Inhalation Powder

Taken by inhalation through your mouth.

Active substances: Each hard capsule contains 100 micrograms beclometasone dipropionate, 6 micrograms formoterol fumarate dihydrate. With each inhalation, 81.9 mcg beclometasone dipropionate and 5 mcg formoterol fumarate dihydrate are delivered to the patient.

Excipient(s): Lactose monohydrate (Inhalac 250) (from bovine milk), lactose monohydrate (Inhalac 400) (from bovine milk), HPMC Capsule (No:3) composition: hypromellose, azorubine.

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

In this leaflet:

- 1. What FOREBEC is and what it is used for***
- 2. What you need to know before you use FOREBEC***
- 3. How to use FOREBEC***
- 4. Possible side effects***
- 5. How to store FOREBEC***

1. WHAT FOREBEC IS AND WHAT IT IS USED FOR

- FOREBEC is an inhaler type of medicine that is inhaled through the mouth and provides the delivery of dry powdered active substances to the airways in the lungs.
- FOREBEC is supplied with 120 capsules and 1 device (monodose dry powder inhaler). Each capsule contains 100 mcg beclometasone dipropionate and 6 mcg formoterol fumarate dihydrate.
- FOREBEC contains two separate active substances, beclometasone dipropionate and formoterol fumarate dihydrate:
 - The first active substance, beclometasone dipropionate, belongs to a group of medicines called corticosteroids that relieves the infection/inflammation of the airways in the lungs and relieves swelling, tenderness and inflammation of the airway walls in the lungs.
 - The second active substance, formoterol fumarate dihydrate, belongs to a group of medicines called long-acting bronchodilators (bronchial expanders) and relaxes the muscles of the airway walls in the lungs, allowing them to expand.

FOREBEC is regularly used in the treatment of asthma and COPD from the age of 18. It is used in the treatment of asthma in order to correct and control asthma symptoms starting from the third step, and to reduce the symptoms and frequency of attacks in moderate and severe COPD patients.



2. WHAT YOU NEED TO KNOW BEFORE YOU USE FOREBEC

Do not use FOREBEC

- If you are hypersensitive to the active substances and/or other ingredients in FOREBEC,
- Do not use this medicine if you are experiencing symptoms of acute asthma such as shortness of breath, wheezing or coughing, if your asthma is worsening or if you are having an acute asthma attack. You should always have your quick-acting "reliever" inhaler with you at all times, in order to alleviate these sudden asthma symptoms.

Take special care with FOREBEC

- If you have any heart problems, such as angina (heart pain, pain in the chest), a recent 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).
- If you have heart rhythm disorders such as increased or irregular heart rate, heart valve disorders, or certain electrocardiogram abnormalities or other heart diseases.
- If you have high blood pressure.
- If you have narrowing of the arteries (occlusive arterial diseases especially arteriosclerosis), or if you know that you have an abnormal bulging of the blood vessel wall (aneurysm).
- If you have an overactive thyroid gland (thyrotoxicosis).
- If you have low blood levels of potassium (hypokalemia).
- If you have any disease of your liver or kidneys.
- If you have diabetes mellitus (if you inhale 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).
- If you have a tumor of the adrenal gland, that is, of the adrenal cortex (pheochromocytoma).
- If you are due to have an anesthetic, please tell your doctor that you are using FOREBEC. Depending on the type of anesthetic, it may be necessary to stop using FOREBEC at least 12 hours before the anesthesia.
- If you are being, or have ever been, treated for tuberculosis (TB) or if you have a known viral or fungal infection of your chest.
- If you drink alcohol for any reason.
- Rarely, serious and sometimes fatal asthma-related breathing problems may occur due to long-acting beta-agonist preparations (e.g. formoterol, salmeterol).
- FOREBEC is not recommended for the initial treatment of asthma.
- Long-acting beta-agonist preparations (e.g. formoterol, salmeterol) should be used for the shortest period of time that provides symptom control for asthma, and your doctor will stop your medication once asthma control is reached, if possible. Afterwards, your doctor will ensure its continuity with a treatment that provides control.
- If you are a pediatric or adolescent patient using a long-acting beta-agonist (e.g. formoterol, salmeterol) in addition to an inhaled corticosteroid (e.g. ciclesonide, fluticasone, budesonide), your doctor will advise you to use a combination preparation containing both an inhaled corticosteroid (e.g. ciclesonide, fluticasone, budesonide) and a long-acting beta-agonist (e.g. formoterol, salmeterol) to ensure compliance with both drugs.
- If you are in a period of exacerbation or if you have severe or acutely worsening asthma, treatment with long-acting beta agonists (e.g. formoterol, salmeterol) should not be started.



If any of the above applies to you, always inform your doctor before using FOREBEC.

If you are not sure that you can use FOREBEC, consult your doctor or pharmacist before using it.

If your doctor decides to stop your treatment, this will be done by reducing the dose of your medicine. Do not stop the medicine suddenly. Even if all the symptoms of your disease have disappeared, continue to use FOREBEC until your doctor says that you need to stop taking it.

Be sure to consult your doctor if you think that the treatment is not working well or your disease is getting worse after starting treatment with FOREBEC, if you have increased the use of "reliever" bronchodilators, or if you experience a sudden increase in wheezing, coughing and shortness of breath after taking your dose.

If you have severe asthma, you should receive special care. The lack of oxygen in the blood combined with some other treatments (diuretics used to treat heart disease or high blood pressure, or other medicines used to treat asthma) you may be taking together with FOREBEC can lower potassium levels. For this reason, your doctor may want to measure the potassium levels in your blood from time to time.

If you are using an inhaler to take high doses of corticosteroids over a long period of time, you may have more of a need for corticosteroids in situations of stress. Stressful situations might include being taken to hospital after an accident, having a serious injury, or before an operation. In this case, the doctor treating you will decide whether you may need to increase your dose of corticosteroids and may prescribe some 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 FOREBEC and any medicines or tablets bought without a prescription, in their original package, if possible.

If blurred vision or other visual disturbances occur while using FOREBEC, consult an eye doctor immediately.

Systemic effects may occur in long-term treatment at high doses with inhaled corticosteroids. These effects are less likely to occur than with oral (taken by mouth) corticosteroids. Possible systemic effects are: some adrenal gland diseases (Cushing's syndrome, Cushingoid symptoms) manifested by weight gain, rounding of the face and increase in blood pressure, or a condition in which the adrenal glands cannot produce enough steroid hormones (adrenal suppression); growth retardation in children and teenagers; decrease in bone mineral density; cataracts; increased eye pressure (glaucoma); and, more rarely, a range of psychological or behavioral disorders, including physical and mental hyperactivity (psychomotor hyperactivity), sleep disturbances, excessive worry (anxiety), depression or aggression. It is therefore important that the dose of inhaled corticosteroids be adjusted by your doctor to the lowest dose at which asthma is effectively controlled.

To reduce the risk of fungal infections of the mouth or throat, or hoarseness (dysphonia) due to the use of FOREBEC, rinse your mouth or gargle with water, or brush your teeth after using the medicine.

Please consult your doctor, even if these warnings were applicable to you at any time in the past.

Using FOREBEC with food and drink



FOREBEC does not have any known interactions with food.

However, you should avoid drinking alcohol unless you first talk to your doctor. Alcohol can reduce your heart's tolerance to formoterol, one of the active ingredients of FOREBEC.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

There is no clinical information on the use of FOREBEC during pregnancy.

If you think you are pregnant or are planning to become pregnant, please consult your doctor. You should only use FOREBEC during pregnancy if advised by your doctor, as studies in pregnant animals have shown that high doses of corticosteroids cause developmental disorders such as cleft palate and intrauterine growth retardation.

If you realize you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide if you should stop using FOREBEC while breastfeeding or avoid breastfeeding while using FOREBEC. Always strictly follow your doctor's advice.

Driving and using machines

FOREBEC is not expected to affect your ability to drive or operate machinery.

However, if you experience side effects such as dizziness and/or tremors, your ability to drive or operate machinery may be affected.

Important information about some ingredients of FOREBEC

FOREBEC contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines

Before starting treatment, please inform your doctor or pharmacist of any other medicines you are currently taking or have recently taken, including medicines obtained without a prescription.

If you are using medicines containing ritonavir or cobicistat as active ingredients, used in the treatment of AIDS, be sure to inform your doctor because these medicines may increase the effects of FOREBEC.

Do not use FOREBEC together with medicines called beta-blockers (drugs used in the treatment of hypertension and/or coronary artery disease containing active substances such as atenolol, carvedilol, propranolol, metoprolol, nebivolol, etc., and medicines containing timolol used in the treatment of increased eye pressure), which are used to treat many diseases, including heart-related problems, high blood pressure and increased eye pressure (glaucoma). If you need to use beta-blockers (including eye drops), the effect of formoterol may be reduced or formoterol may not work at all.

- Other medicines that work in the same way as formoterol (i.e. beta-adrenergic drugs used to treat asthma in general) may increase the effects of formoterol.
- Medicines for treating abnormal heart rhythms (e.g. quinidine, disopyramide, and procainamide), certain antihistamines for treating allergic reactions (e.g. terfenadine), medicines for treating the



symptoms of depression or mental disorders such as monoaminoxidase inhibitors and tricyclic antidepressants (e.g. phenelzine, isocarboxazid, amitriptyline and imipramine or 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), to treat an underactive thyroid gland (L-thyroxine), or medicines containing oxytocin (which causes uterine contraction) and alcohol can lower your heart's tolerance to beta-2 agonists, such as formoterol.
- Monoaminoxidase inhibitors (MAOIs) used to treat mental disorders, including medicines such as furazolidone (used to treat bowel infections or diarrhea) and procarbazine (used to treat tumors) can cause a rise in blood pressure.
- Medicines for treating heart disease (digoxin) can cause a fall in your blood potassium level. This may increase the likelihood of abnormal heart rhythms.
- Other medicines used to treat asthma (theophylline, aminophylline or steroids) and diuretics (water tablets) may cause a fall in your potassium level.
- Some anesthetics can increase the risk of abnormal heart rhythms.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO USE FOREBEC

Instructions for proper use and dose/administration frequency

Always use FOREBEC as prescribed by your doctor. Ask your doctor or pharmacist if you are not sure how to use it.

Your doctor will check you regularly to make sure you are taking the correct dose of FOREBEC. Once your disease is well controlled, your doctor may decide that the dose of FOREBEC needs to be reduced gradually.

In the treatment of asthma

If you experience coughing, wheezing, or shortness of breath while using FOREBEC, these symptoms may mean that your condition is not fully controlled and your doctor may prescribe FOREBEC as an addition to your daily treatment or may order you to use FOREBEC with an additional "reliever" inhaler.

Using FOREBEC together with a separate "reliever":

The recommended dose of this medicine for adults 18 years of age and older and for the elderly is 1 or 2 inhalations (breathing into the lungs) twice daily. The maximum daily dose is 4 inhalations.

You should always have your reliever inhaler with you to treat worsening symptoms of asthma or sudden asthma attacks.

In the treatment of COPD (Chronic Obstructive Pulmonary Disease)

The recommended dose of this medicine for adults 18 years of age and older and for the elderly is 2 inhalations in the morning and 2 inhalations in the evening.

You should never change your treatment dose without speaking with your doctor. You should not increase your treatment dose either. You should definitely consult your doctor if you feel that the medicine is not effective.



If your breathing does not improve:

If your symptoms do not improve after using FOREBEC, you may be using the inhaler incorrectly. Therefore, read and check the instructions for correct use of the device under the heading “Route and method of administration” and/or contact your doctor to be properly trained again.

If your symptoms worsen:

If your symptoms/signs get worse or if your reliever inhaler does not improve your symptoms or if your symptoms become difficult to control (e.g. if you use your "reliever" inhaler more often), you should see your doctor immediately to determine the effectiveness of your treatment on your symptoms. Your disease may have worsened and your doctor may have to change your treatment dose or prescribe another medicine for you.

Route and method of administration

The device allows you to inhale your medicine through your mouth.

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

After inhaling the dose, it is important to rinse your mouth with water or brush your teeth in order to prevent inflammation in the mouth.

Please read all instructions below before using this inhaler.

If you have any problems while using this inhaler, please contact your doctor or pharmacist.

Package Contents

This package contains the following:

- 120 capsules
- 1 monodose dry powder inhaler
- 1 package leaflet

If the contents of the package are not the same as above, return your inhaler to your pharmacist and ask for a new one.

General Warnings and Precautions

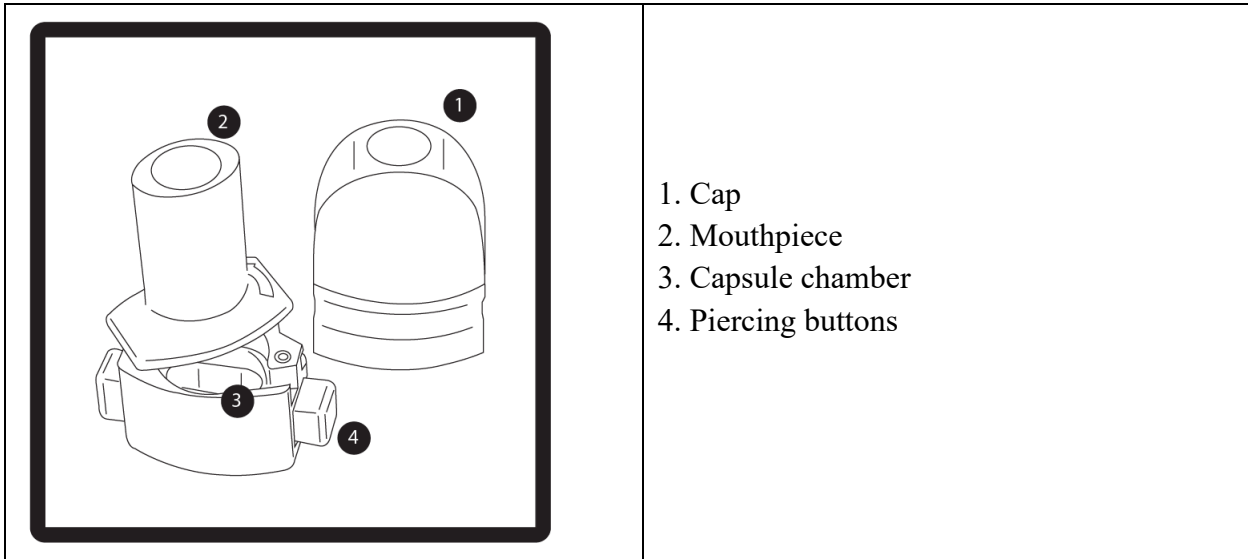
- Use your inhaler only as indicated.
- If you are not sure you are receiving your dose correctly contact your pharmacist or doctor.
- If you are not sure of inhaling your dose, wait until your next scheduled dose and take this as normal. Do not take an extra dose.
- Keep the cover closed until you need to take a dose from your inhaler.
- When you are not using your inhaler, keep it in a clean and dry place.
- **Do not** attempt to take your inhaler apart for any reason.

Do not use your inhaler in the following situations:

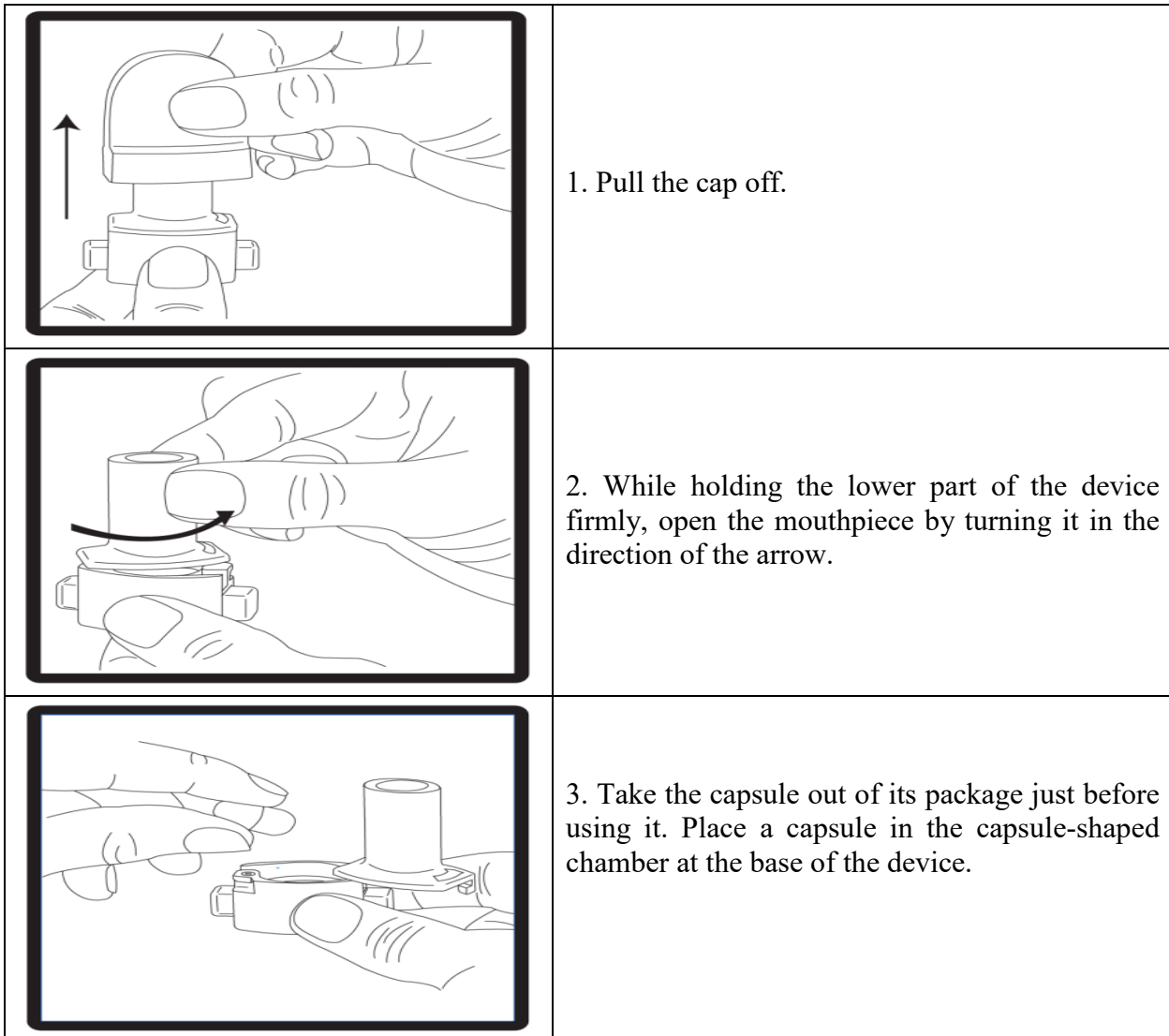
- After the expiry date written on the box,
- If your device is broken.

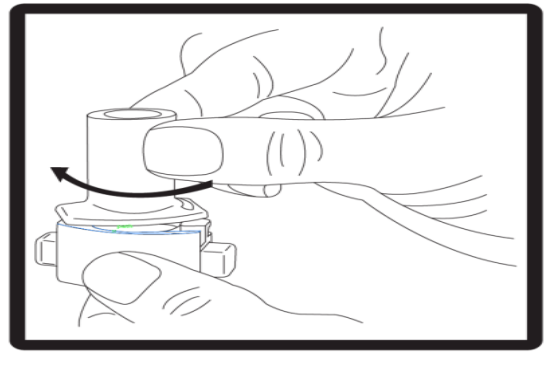
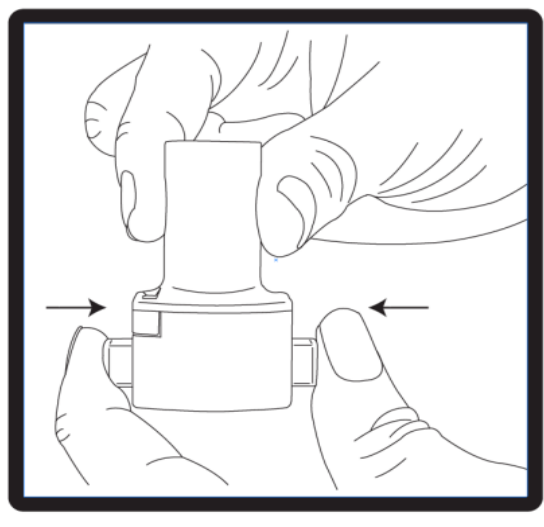
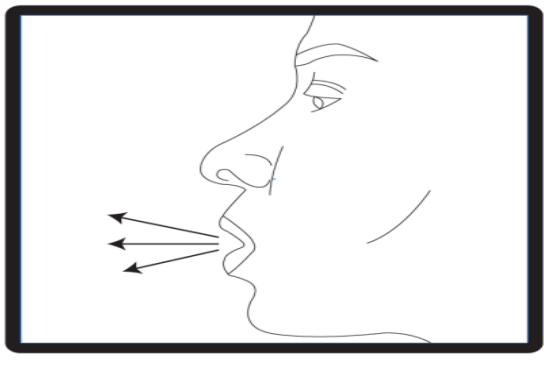
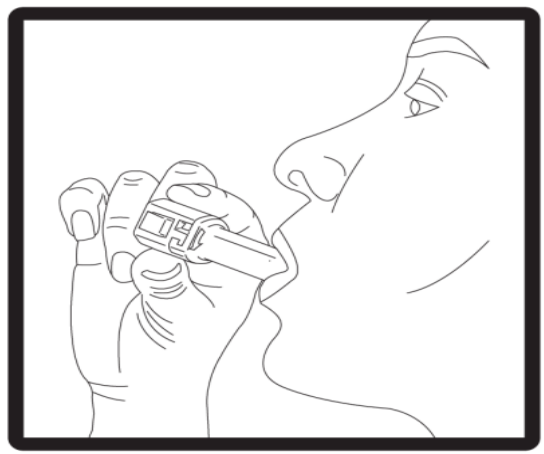
Dispose of your inhaler or consult your pharmacist according to the conditions mentioned above. Ask your pharmacist how to dispose of inhalers that are no longer needed.

Parts of the Inhaler



Instructions for use:



	<p>4. Twist the mouthpiece to close it.</p>
	<p>5. Hold the device upright (mouthpiece up) and simultaneously press the side buttons ONLY ONCE. Leave the buttons after the capsule is pierced. Please note: During this procedure, the capsule may break apart and there is a possibility of small capsule fragments getting into the mouth and throat during inhalation. The fragments of the capsule are harmless. Unpacking the capsule just before use and pressing the side tabs only once to burst the capsule minimizes the risk of capsule rupture (see step 3).</p>
	<p>6. Breathe out as slowly and deeply as possible.</p>
	<p>7. Place the mouthpiece in your mouth and tilt your head back slightly. Close your lips tightly around the mouthpiece and take a deep breath as quickly and deeply as you can. As the powder disperses, you will hear a "buzz" sound caused by the capsule spinning in its chamber. If you have not heard this sound, the capsule may be stuck in the capsule chamber. In this case, open the device and loosen the capsule by moving it in its chamber. DO NOT press the buttons more than once to loosen the capsule.</p>



8. Hold your breath:

As you remove the inhaler from your mouth, **hold your breath** for 5-10 seconds or as long as possible, and then breathe out.

Open the inhaler to check if there is any powder left in the capsule. If there is any powder left in the capsule, close the inhaler and repeat steps 6, 7 and 8. Most patients empty the capsule after one or two inhalations.

Some people seldom cough for a short time after taking the medicine by inhalation. Do not worry if you cough. If the capsule is empty, it means that you have taken the full dose of your medicine.

After each inhalation, in order to reduce the risk of a possible candida (fungal) infection, it is advised to rinse the mouth thoroughly with water and then spit it out.

9. Discard the empty capsule after use and close the mouthpiece.

Cleaning

- In fact, your inhaler does not need to be cleaned.
- If necessary, you can clean your inhaler with a dry cloth or tissue after you use it.
 - **Do not** clean your inhaler with water or any other liquid. Keep it dry!

Storage

- Keep your inhaler somewhere clean and dry.
- Do not expose your inhaler to heat or direct sunlight.
 - Do not leave your inhaler in damp or wet conditions.
- Keep it out of the sight and reach of children.

Disposal

- Ask your pharmacist to dispose of medicines you have finished or no longer need.
 - Do not dispose of medicines together with your normal household waste.

Different age groups

Use in children

Not recommended for adolescents and children under 18 years of age.

Use in elderly

No dose adjustment is required in elderly patients.

Use in special conditions

Kidney/Liver failure

There is no data available on the use of FOREBEC in people with liver or kidney problems.

Tell your doctor or pharmacist if you think that the effect of FOREBEC is too strong or too weak.

If you take more FOREBEC than you should

- Consult your doctor immediately or go to the emergency department of the nearest hospital to you. Take all the medicines you are using as well.
- Side effects may develop. Tell your doctor if you have any unusual symptoms, as your doctor may



carry out additional tests or decide on any other measures that may be necessary.

- Taking more formoterol than you should can have the following effects: nausea, vomiting, trembling, feeling sleepy, palpitations, heart racing (tachycardia), disturbances of heart rhythm (ventricular arrhythmia), confusion, sluggishness, sleep disorders; a condition (metabolic acidosis) manifested by nausea, vomiting, headache; low blood potassium levels (hypokalemia), high levels of sugar in the blood (hyperglycemia).
- Taking too much beclometasone dipropionate can lead to short-term problems such as swelling in the body or weight gain due to suppression of your adrenal glands. However, this will get better within a few days.

If you have taken more FOREBEC than you should please consult your doctor or pharmacist.

If you forget to use FOREBEC

Take your medicine 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 replace the missed dose.

Possible effects when stop using FOREBEC

Do not lower the dose or stop using your medicine without asking your doctor, because the dose should gradually be stopped under the supervision or with the advice of your doctor, the medication should not be stopped abruptly.

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, FOREBEC can cause side effects in patients allergic to its ingredients.

As with other inhaler treatments, there is a risk of worsening shortness of breath, cough and wheezing immediately after using FOREBEC and this is known as **paradoxical (unexpected) bronchospasm**. If this occurs, you should **STOP using FOREBEC immediately** and use your **quick-acting “reliever” inhaler** straightaway to treat the symptoms. You should also contact your doctor straightaway.

Stop using FOREBEC and tell your doctor immediately or go to the nearest hospital emergency department if you experience any of the following:

- Allergic reactions such as 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.

These are all very serious side effects.

If you experience any of these, it means that you are severely allergic to FOREBEC.

You may need emergency medical attention or hospitalization.

These very serious side effects are seen very rarely.



Other possible side effects that you may experience during treatment with FOREBEC are listed below according to their frequency.

If you notice any of the following, tell your doctor right away or go to the nearest hospital emergency department:

Adverse events were classified according to the following frequencies:

- Very common : may occur in at least 1 in 10 patients.
- Common : may occur less than 1 in 10 patients, but more than 1 in 100 patients.
- Uncommon : may occur less than 1 in 100 patients, but more than 1 in 1,000 patients.
- Rare : may occur less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
- Very rare : may occur less than 1 in 10,000 patients.
- Not known : frequency cannot be estimated from the available data.

Common

- Trembling
- Pneumonia (infection of the lungs) in patients with COPD

Tell your doctor if you have any of the following while using FOREBEC, as they could be symptoms of a lung infection:

- Fever or chills
- Increased mucus production (phlegm-like airway secretion), change in mucus color
- Increased cough or increased breathing difficulties

Uncommon

- Worsening of your asthma symptoms
- Difficulty breathing, shortness of breath (dyspnea)
- Unusually fast or slow heart beat
- Changes in the electrical conduction graph (electrocardiogram/ECG) of your heart
- High level of potassium in your blood
- High level of glucose in your blood
- High level of fats in your blood (hypertriglyceridemia)
- Chest pain
- Low level of cortisol in your urine or in your blood
- Dry throat, fungal infection or pain in the mouth or throat (oropharyngeal infection or pain) (rinsing your mouth or gargling with water, and brushing your teeth immediately after each inhalation may help to prevent these side effects)
- Cough
- Cold-like symptoms
- Sore throat
- Hoarseness
- Speech disorders (dysphonia)
- Nausea
- Headache
- Feeling sick
- Feeling tired or nervous

Not known

- Physical and mental hyperactivity (psychomotor hyperactivity)



- Sleeping disorders
- Feeling too worried (anxiety)
- Depression
- Aggression
- Behavioral changes
- Restlessness
- Blurred vision

These are all serious side effects. Emergency medical attention may be required.

Side effects that have been observed with similar medicines for inhalation containing beclometasone dipropionate and/or formoterol are:

- Palpitations
- Uneven heartbeat
- Abnormal or impaired sense of taste
- Muscle pain and muscle cramps
- Restlessness
- Dizziness
- Feeling anxious
- Sleep disorders
- A fall in the level of potassium in the blood
- Increase or decrease of blood pressure

Using high-dose inhaled corticosteroids over a long time can cause systemic effects these include:

- Problems with how your adrenal glands work (adrenosuppression)
- Decrease in bone mineral density
- Growth retardation in children and adolescents
- Increased pressure in your eyes (called glaucoma), cataracts
- Rapid weight gain, particularly of the face and torso
- Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable (these effects are more likely to occur in children)
- Abnormal behavior

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FOREBEC

Keep FOREBEC out of the reach and sight of children and in its original package.
Keep this medicine in its original package in order to protect it from moisture.

Store this product at room temperature below 25°C.

Use it in accordance with the expiry date.



Do not use FOREBEC after the expiry date that is stated on the package.

Do not use FOREBEC if you notice any defect in the product and/or on its package.

For further information on the storage of this inhaler, please read the instructions given in the section 3 of this package leaflet.

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.

Marketing Authorization Holder

DEVA Holding A.Ş.

Küçükçekmece - ISTANBUL/TURKEY

Manufacturing Site:

DEVA Holding A.Ş.

Kapaklı - TEKIRDAG/TURKEY

This package leaflet was approved on 01/02/2022.