**Package leaflet: Information for the patient**

**Forobec 100 micrograms/6 micrograms per actuation pressurised inhalation solution**
beclometasone dipropionate/formoterol fumarate dihydrate

**Read all of this 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What <Product Name> is and what it is used for

<Product Name> 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 are beclometasone dipropionate and formoterol fumarate dihydrate. Beclometasone dipropionate belongs to a group of medicines called corticosteroids which have an anti-inflammatory action reducing the swelling and irritation in your lungs.

Formoterol fumarate dihydrate belongs to a group of medicines called long-acting bronchodilators which relax the muscles in your airways and helps you to breathe more easily.

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

Asthma
<Product Name> is indicated in the regular treatment of asthma in adult patients in whom:
- asthma is not adequately controlled by using inhaled corticosteroids and “as needed” short-acting bronchodilators or
- asthma is responding well to treatment with both corticosteroids and long-acting bronchodilators.

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

## 2. What you need to know before you use <Product Name>

**Do not use <Product Name>**

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

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before using <Product Name> if you have any of the following:

• 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 cardio-myopathy (also known as HOCM, a condition where the heart muscle is abnormal).
• 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).
• disorders of your 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.
• an overactive thyroid gland.
• low blood levels of potassium.
• any disease of your liver or kidneys.
• diabetes (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 treat-ment).
• a tumour of the adrenal gland (known as a phaeochromocytoma).
• if you are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking <Product Name> at least 12 hours before the anaesthesia.
• 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 must avoid alcohol for any reason

**If any of the above applies to you, always inform your doctor before you use <Product Name>.**
If you have or had any medical problems or any allergies or if you are not sure as to whether you can use <Product Name> talk to your doctor, asthma nurse or pharmacist before using this medicine.

Treatment with a beta-2-agonist like the formoterol contained in <Product Name> can cause a sharp fall in your serum potassium level (hypokalaemia).

**If you have severe asthma, you should take special care**. This is because a lack of oxygen in the blood and some other treatments you may be taking together with <Product Name>, such as medicines for treating heart disease or high blood pressure, known as diuretics or “water tablets” or other medicines used to treat asthma can make the fall in potassium level worse. For this reason, your doctor may wish to measure the potassium levels in your blood from time to time.

If you take higher doses of inhaled corticosteroids over long periods, 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 <Product Name> and any medicines or tablets bought without a prescription, in their original package, if possible.

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

**Children and adolescents**

<Product Name> should not be used in children and adolescent less than 18 years old, until further data become available.

**Other medicines and <Product Name>:**
Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Some medicines may increase the effects of <Product Name> 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**. 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 other beta-adrenergic drugs (drugs which work in the same way as formoterol) may increase the effects of formoterol.

Using <Product Name> 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 monoaminoxidase inhibitors (for example phenelzine and isocarboxazid), tricyclic antidepressants (for example amitryptiline and imipramine), 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), 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), 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 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 anaesthetics can increase the risk of abnormal heart rhythms.

**Pregnancy, breast-feeding and fertility**
There are no clinical data on the use of <Product Name> during pregnancy.
<Product Name> 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**
<Product Name> is unlikely to affect your ability to drive and use machines.

**<Product Name> contains alcohol**
<Product Name> contains 7 mg of alcohol (ethanol) in each actuation which is equivalent to 0.20 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 to use <Product Name>

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

**Asthma**

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of <Product Name>. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms.

<Product Name> can be prescribed by your doctor in two different ways:
a) use <Product Name> 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 <Product Name> every day to treat your asthma and also use <Product Name> to treat sudden worsening of your asthma symptoms, such as shortness of breath, wheezing and cough

**a) Using <Product Name> together with a separate "reliever":**

Adults and the elderly
The recommended dose 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 <Product Name> as your only asthma inhaler:**
Adults and the elderly
The recommended dose is one puff in the morning and one puff in the evening.

You should also use <Product Name> 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 <Product Name> 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 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 and the elderly
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 <Product Name> in people with liver or kidney problems.

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

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

**If you use more <Product Name> than you should:**
• 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 (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 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 forget to use <Product Name>:**
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 stop using <Product Name>**
Do not lower the dose or stop using the medication.
Even if you are feeling better, do not stop using <Product Name> or lower the dose. If you want to do this, talk to your doctor. It is very important for you to use <Product Name> 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.

**If your breathing gets worse:**
If you develop worsening shortness of breath or wheezing (breathing with an audible whistling sound), straight after inhaling your medicine, stop using <Product Name> inhaler immediately and use your quick-acting “reliever” inhaler straightaway. You should contact your doctor straightaway. Your doctor will assess your symptoms and if necessary may start you on a different course of treatment. See also section 4.Possible side effects

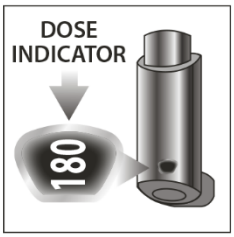
**If your asthma gets worse:**
If your symptoms get worse or are difficult to control (e.g. if you are using a separate "reliever" inhaler or <Product Name> as reliever inhaler more frequently) or if your "reliever" inhaler or <Product Name> does not improve your symptoms, see your doctor immediately. Your asthma may be getting worse and your doctor may need to change your dose of <Product Name> or prescribe alternative treatment.

<u>Method of administration</u>

<Product Name> is for inhalation use.

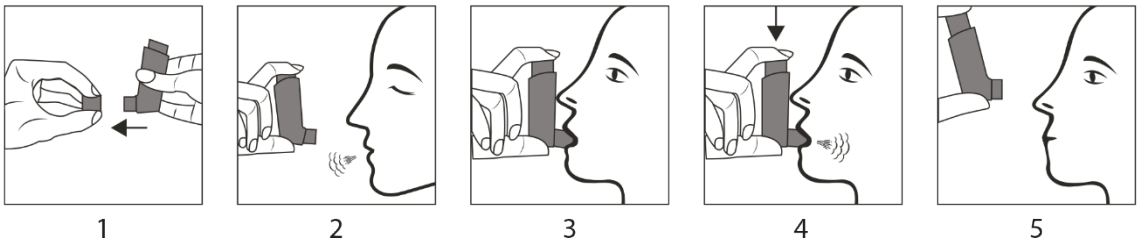
This medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.
There is a counter (or dose indicator) on the back of the inhaler, which tells you how many doses (or puffs) are left. Each time you press the canister, a puff of medicine is released and the counter will count down by one (or the dose indicator rotates by a small amount. The number of puffs remaining is displayed in intervals of 20). 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.
1. Remove the protective cap from the mouthpiece.
2. Hold your inhaler upright with the mouthpiece at the bottom.
3. Direct the mouthpiece away from yourself and firmly depress the canister to release one puff.
4. Check the dose counter (or inidicator). If you are testing your inhaler for the first time, the counter (or inidicator) should read 120 or 180.


**How to use your inhaler**
Whenever possible, stand or sit in an upright position when inhaling.

Before start inhaling, check the dose counter (or indicator): any number between “1” and “120” or “180” shows that there are doses left. If the dose counter (or indicator) 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 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. 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 breath into the inhaler.

If you need to take another puff, keep the inhaler in the vertical position for about half a minute, then repeat steps 2 to 5.

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

After use, close with the protective cap and check the dose counter (or inidicator).
To lower the risk of a fungal infection in the mouth and throat, rinse your mouth or gargle with water or brush your teeth each time you use your inhaler.

You should get a new inhaler when the counter (or inidicator) shows the number 20. Stop using the inhaler when the counter shows 0 as any puffs left in the device may not be enough to give you a full dose and start using the new inhaler.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that <Product Name> 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 <Product Name> is too much or not enough, tell your doctor or pharmacist.

If you find it difficult to operate the inhaler while starting to breathe in you may use the Aerochamber Plus™ spacer device. Ask your doctor, pharmacist or a nurse about this device.
It is important that you read the package leaflet which is supplied with your AeroChamber Plus™ spacer device and that you follow the instructions on how to use the AeroChamber Plus™ spacer device and how to clean it, carefully.

**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.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

As with other inhaler treatments there is a risk of worsening shortness of breath and wheezing immediately after using <Product Name> and this is known as paradoxical bronchospasm. If this occurs, **you should STOP using <Product Name> 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.

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.

Other possible side effects are listed below according to their frequency.

**Common: may affect up to 1 in 10 people**
- Fungal infections (of the mouth and throat), headache, hoarseness, sore throat.
- Pneumonia in COPD patients: tell your doctor if you have any of the following while taking <Product Name> as they could be symptoms of a lung infection:
    - fever or chills
    - increased mucus production, change in mucus colour
    - increased cough or increased breathing difficulties

**Uncommon: may affect up to 1 in 100 people**
- palpitations
- unusual fast heartbeat and disorders of heart rhythm some 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
- 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:
    - 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 level
    - increase in the blood level of insulin, free fatty acid and ketones.

**The following side effects have also been reported as "uncommon" in patients with Chronic Obstructive pulmonary disease":**

- Reduction of the amount of cortisol in the blood; this is caused by the effect of corticosteroids on your adrenal gland
- irregular heartbeat

**Rare: may affect up to 1 in 1 000 people**

- Feeling chest tightness, missed heartbeat (caused by too early contraction of the ventricles of the heart), increased or decrease in blood pressure, inflammation of the kidney, swelling of skin and mucous membrane persisting for several days

**Very rare: may affect 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.

**Not known: frequency cannot be estimated from the available data**

- Blurred vision

**Using high-dose 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 mineral density (thinning of the bones), growth retardation in children and adolescents, increased pressure in your eyes (glaucoma), cataracts.
- Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable: these events are more likely to occur in children but the frequency is unknown.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting

system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store <Product Name>

Keep this medicine out of the sight and reach of children.

For the pharmacist:
Store in a refrigerator (2-8 °C) for a maximum of 18 months.

For the patients:
Do not use this medicine beyond 3 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 after Exp.
The expiry date refers to the last day of that month.
Do not store the inhaler above 25 °C.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What <Product Name> contains**
The active substances are beclometasone dipropionate and formoterol fumarate dihydrate.
Each actuation/metered dose from the inhaler contains 100 micrograms of beclometasone dipropionate and 6 micrograms of formoterol fumarate dihydrate. This corresponds to a delivered dose from the mouthpiece of 84.6 micrograms of beclometasone dipropionate and 5.0 micrograms of formoterol fumarate dihydrate.

The other ingredients are: norflurane (HFA 134-a), ethanol anhydrous, hydrochloric acid.

**What <Product Name> looks like and contents of the pack**
<Product Name> is a pressurised solution contained in a 19 ml pressurised aluminium container sealed with a metering valve and fitted into a white plastic actuator which incorporates a dose counter (120 actuations pack) or a dose indicator (180 actuations pack), with a light blue plastic protective cap.

This medicine contains fluorinated greenhouse gases.

For 120 actuations: Each inhaler contains 8,07 g of 1,1,1,2-Tetrafluoroethane corresponding to 0,0115 tonne $CO_2$ equivalent (global warming potential GWP = 1430).

For 180 actuations: Each inhaler contains 11,40 g of 1,1,1,2-Tetrafluoroethane corresponding to 0,0163 tonne $CO_2$ equivalent (global warming potential GWP = 1430).

Each pack contains:
1 pressurised container (which provides 120 actuations)
2 pressurised containers (which provide 120 actuations each)
3 pressurised containers (which provide 120 actuations each)
1 pressurised container (which provides 180 actuations)

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
<[To be completed nationally]>

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

<[To be completed nationally]>

**This leaflet was last revised in 6 Nov 2025**

<[To be completed nationally]>

<Other sources of information>

<Latest approved information on this medicine is available by scanning the QR code included in the <package leaflet> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website>>