**Package leaflet: Information for the user**

**Befoair 100 micrograms/6 micrograms/actuation, pressurised inhalation, solution**

beclometasone dipropionate/formoterol fumarate dihydrate

**Read all of this leaflet carefully before you start using 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 Befoair is and what it is used for

Befoair 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, which belongs to a group of medicines called corticosteroids that have an anti-inflammatory action reducing the swelling and irritation in your lungs.

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

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

Asthma
Befoair is indicated for the regular treatment of asthma in adult patients in whom:
- asthma is not adequately controlled with inhaled corticosteroids and as-needed short-acting bronchodilators

or
- asthma is responding well to treatment with corticosteroids and long-acting bronchodilators.

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

## 2. What you need to know before you use Befoair

**Do not use Befoair**
- 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 Befoair if you have any of the following:**
- heart problems, such as angina pectoris (heart pain, pain in the chest), a recent heart attack, heart failure, coronary artery disease (stenosis), valvular heart disease or other heart abnormality, or if you know you have hypertrophic obstructive cardiomyopathy (a condition with abnormalities of the heart muscle)
- if you have arterial stenosis (also known as arteriosclerosis), if you have high blood pressure or if you know you have an aneurysm (abnormal bulging of the artery wall)
- if you have heart rhythm problems (your heartbeat is increased or irregular), a fast heart rate or palpitations, or you have been told that your heart curve 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. When you start using this medicine and from time to time during treatment you may need to have some additional blood tests to check your blood sugar).
- tumour of the adrenal gland (known as a phaeochromocytoma)
- are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking Befoair for 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 Befoair.**

If you have or had any medical problems or allergies or if you are not sure whether you can use Befoair talk to your doctor, asthma nurse or pharmacist before using this medicine.

**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 Befoair 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 Befoair can make the fall in potassium level worse.

**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 Befoair and any medicines or tablets bought without a prescription, in their original packaging, if possible.

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

**Children and adolescents**
Befoair must not be used in children and adolescent less than 18 years old.

**Other medicines and Befoair**
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. This is because Befoair may affect the way some other medicines work. Also, some medicines may affect the way Befoair works.

Using Befoair concomitantly with:
- the HIV medicines ritonavir and cobicistat, and some other merdicines, may increase the effects of Befoair and your doctor may wish to monitor you carefully
- beta-blocker medicines, including eye drops, can reduce the effect of formoterol or formoterol may not work at all. Beta blockers are medicines used to treat many conditions including heart problems, high blood pressure and glaucoma (increased pressure in the eyes).
- beta adrenergic medicines (medicines which work in the same 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) or medicines for treating symptoms of depression or mental disorders such as monoaminoxidase inhibitors (for example phenelzine and isocarboxazid), tricyclic antidepressants (for example amitriptyline and imipramine), or phenothiazines can cause certain changes in the electrocardiogram (ECG, heart trace). They may also increase the risk of heart rhythm disturbances (ventricular arrhythmias).
- medicines to treat Parkinson's disease (L-dopa), medicines to treat an underactive thyroid gland (L-thyroxine), medicines containing oxytocin (which causes uterine contraction) or alcohol can lower your heart's tolerance to beta-2 agonists, such as formoterol
- medicines to treat mental disorders such as monoaminoxidase inhibitors (MAOIs), including medicines with similar properties like furazolidone and procarbazine can cause a rise in blood pressure
- medicines to treat heart disease (digoxin) can cause a fall in your blood potassium level and increase the susceptibility to heart rhythm disturbances
- other medicines used to treat asthma (theophylline, aminophylline or steroids) and diuretics (water tablets) may cause a fall in your potassium level
- some general anaesthetics containing halogenated hydrocarbons (used in operations and dental work) can increase the risk of heart rhythm disturbances.

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

**Befoair contains alcohol**
This medicine contains 7 mg of alcohol (ethanol). in each actuation which is equivalent to 0.2 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 Befoair

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 Befoair. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms.

Befoair can be prescribed by your doctor in two different ways:

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

**a) Using Befoair together with a separate "reliever" inhaler:**

*Adults and the elderly:*
The recommended dose is one or two actuations twice daily.
The maximum daily dose is 4 actuations.

**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 Befoair as your only asthma inhaler:**

*Adults and the elderly:*
The recommended dose is one actuation in the morning and one actuation in the evening.

You should also use Befoair as a "reliever" inhaler to treat sudden asthma symptoms.

If you get symptoms, take one actuation and wait a few minutes. If you do not feel better, take another actuation.
Do not take more than 6 reliever actuations per day.

The maximum total daily dose is 8 actuations.
Contact your doctor if you feel you need more actuations each day to control your asthma symptoms. Your doctor may need to change your treatment.

Chronic obstructive pulmonary disease (COPD)

*Adults and the elderly:*
The recommended dose is two actuations in the morning and two actuations in the evening.

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

**Use in children and adolescents less than 18 years of age:**
Children and adolescents aged less than 18 years must NOT take this medicine.

**Befoair 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 Befoair 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.

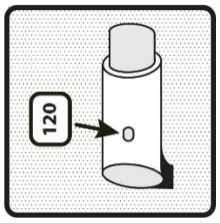
**If your breathing gets worse:**
If you develop worsening shortness of breath or wheezing (breathing with an audible whistling sound) straight after using your inhaler, stop using Befoair immediately and use your rapid acting reliever inhaler straightaway. Contact your doctor straightaway. Your doctor will assess your symptoms and if necessary, prescribe a different 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 Befoair as "reliever" inhaler more frequently) or if your "reliever" inhaler does not improve your symptoms, see your doctor immediately. Your asthma may be getting worse and your doctor may need to change your dose of Befoair or prescribe alternative treatment.

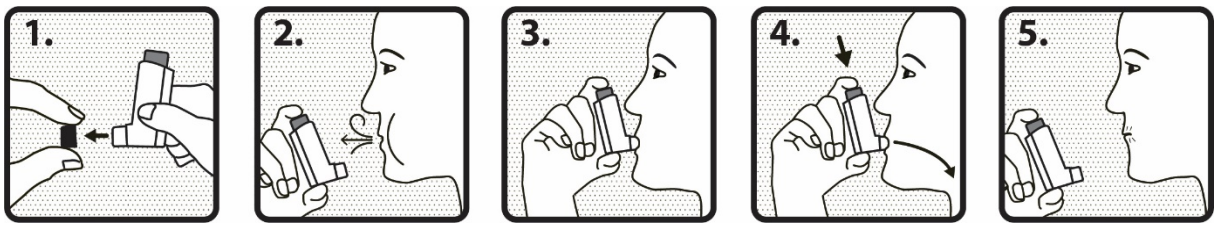
**Method of administration:**
**Befoair is for inhalation use**
This medicine is contained in a pressurised canister in a plastic casing with a mouthpiece. There is a counter on the back of the inhaler, which tells you how many doses are left. Each time you press the canister, a puff of medicine is released 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 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. 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 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 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 actuation.

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.

To take another actuation, 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. 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 Befoair 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.

If you think the effect of Befoair 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 spacer device Aerochamber Plus. Ask your doctor, pharmacist or a nurse about this device. It is important that you read the package leaflet which is supplied with your spacer device Aerochamber Plus and that you follow the instructions on how to use 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.

**If you use more Befoair 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 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 forget to take Befoair**
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.

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

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

## 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 Befoair and this is known as **paradoxical bronchospasm**. If this occurs, you should **STOP using Befoair immediately** and use your quick-acting "reliever" inhaler straightaway to treat the symptoms of shortness of breath and wheezing. You should contact your doctor immediately.

**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.

Uncommon (*may affect up to 1 in 100 people*):
- palpitations, unusually fast heart beat 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
- 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
- diarrhoea
- 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 level
  - increase in the blood level of insulin, free fatty acid and ketones.

Rare (*may affect 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 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

These events are more likely to occur in children:
- sleeping problems
- depression or anxiety
- nervousness
- feeling over-excited or irritable.

The following side effects have also been reported in patients with chronic obstructive pulmonary disease:
- pneumonia (common); 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 (uncommon); this is caused by the effect of corticosteroids on your adrenal gland
- irregular heart beat (uncommon).

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.

**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 Befoair

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.

Store below 25°C for a maximum of 3 months.

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 protect the environment.

## 6. Contents of the pack and other information

**What Befoair contains**
- The active substances are beclometasone dipropionate and formoterol fumarate dihydrate. Each 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 and concentrated hydrochloric acid (for pH adjustment).
- This medicine contains fluorinated greenhouse gases.
  Each inhaler contains 8.15 g of HFA-134a corresponding to 0.012 tonne $CO_2$ equivalent (global warming potential GWP = 1430).

**What Befoair looks like and contents of the pack**
Befoair is a pressurised inhalation solution contained in an aluminium canister with a metering valve, fitted in a plastic actuator which incorporates a dose counter with a plastic protective cap.
Each pack contains:
1 pressurised container (which provides 120 actuations)

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