

## PACKAGE LEAFLET: INFORMATION FOR USER

### FORBEFIX 6/100 mcg inhalation aerosol

#### Used by inhalation.

- *Active substance(s):* 6,00 mcg Formoterol fumarate dihydrate, 100,00 mcg Beclometasone dipropionate
- *Excipient(s):* HFA 227EA, Ethyl Alcohol

**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 more questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Inform your doctor that you are using this medicine, when you go to a hospital or see a doctor while using this medicine.*
- *Comport all information in this leaflet. Do not use **high** or **low** dose besides the dose recommended for you.*

#### **In this leaflet:**

- 1. What FORBEFIX is and what it is used for*
- 2. Before you take FORBEFIX*
- 3. How to use FORBEFIX*
- 4. Possible side effects*
- 5. How to store FORBRFIX*

#### **Titles are included.**

##### **1. What FORBEFIX is and what it is used for?**

FORBEFIX is the inhalator for packaging containing 1 inhaler. Each inhaler contains 120 aerosol puffs.

FORBEFIX contains beclometasone dipropionate and formoterol fumarate in two different drug.

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. Your doctor has prescribed this medication to treat asthma or COPD (chronic obstructive pulmonary disease).

FORBEFIX is used in the treatment of the following diseases:

--- Prevent of breathing problems and bronchodilatation (expansion of the bronchi) in the patients with COPD,

--- Relieve and control symptoms of asthma in the patents with asthma. FORBEFIX is used in two ways for the purpose of asthma treatment.

- In the regular treatment for purpose of asthma symptoms such as shortness of breath, wheezing and coughing.

or

- For the purpose of reliever in the worsening of asthma symptoms such as shortness of breath, wheezing and coughing.

## **2. Before you take FORBEFIX**

### **Do not use FORBEFIX**

- If you are allergic or think you are allergic to one or other of the active ingredients of FORBEFIX or if you are allergic to other medicines or inhalers used to treat asthma or to any of the other ingredients of FORBEFIX and,
- If you are under 18 ages, you must not use FORBEFIX.

### **Use FORBEFIX carefully**

- 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 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).

- If you have disorders of your heart rhythm such as increased or irregular heart rate if you have been told that your heart trace is abnormal.
- If you have an overactive thyroid gland.
- If you have low blood levels of potassium.
- If you have any disease of your liver or kidneys.
- If you have 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 treatment).
- If you have a tumour of the adrenal gland (known as a pheochromocytoma).
- If you are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking FORBEFIX 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 any of the above applies to you, always inform your doctor before you use FORBEFIX**  
Treatment with a beta-2-agonist like the formoterol contained in FORBEFIX 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 FORBEFIX, 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 FORBEFIX 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.

### **Using FORBEFIX with food and drink**

Interaction with food and drink is not expected due to the way FORBEFIX is used.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

There is no clinical information regarding the use of FORBEFIX during pregnancy. Do not take FORBEFIX without telling your doctor if you are pregnant or plan to become pregnant during treatment.

*If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

If you are breastfeeding, use FORBEFIX only if your doctor have decided you to use.

*Consult your doctor or pharmacist before using this medication.*

### **Driving and using machines**

It is not expected that FORBEFIX will have an adverse effect on the ability to drive and use machines.

### **Important information about some of the ingredients of FORBEFIX**

FORBEFIX contains a small amount of ethanol - less than 100 mg per dose-

### **Other medicines and FORBEFIX**

Inform your doctor or pharmacist before you start treatment, if you are taking any medication or if you have recently used it.

- 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 amitriptyline 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 intestinal infections and diarrhea and tumor, 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.

*Please inform your doctor or pharmacist if you are using or have recently used any medicine with or without a prescription.*

### **3. How to use FORBEX**

#### **Instructions for proper use and dose / application frequency:**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The pharmacist’s label will tell you how many puffs to take and how often they must be taken.

Your doctor will check you on a regular basis to make sure you get the optimal dose. Your doctor will adjust the treatment to the lowest dose that best controls the symptoms of your disease. Do not change the dose you are taking without talking to your doctor. FORBEX can be prescribed by your doctor in two different ways:

Adult and elderly the age of 18;

1) “Current dose” application for the purpose of relieve and control symptoms of asthma;

Should use 1 puff twice a day according to the severity of asthma symptoms. The maximum daily dose is 4 puffs.

2) Worsing of asthma symptoms suddenly for “reliever” and in the regular treatment for asthma control;

If your symptoms of asthma got worse, inhale 1 puff and wait a few minutes. If you do not feel well, you're breathing more than 1 puff. Do not inhale more than 6 puffs a day for “reliever” purposes.

Take current FORBEMIX dose regularly as prescribed by your doctor for control of your asthma.

If need more than normal FORBEMIX dose, should consult the doctor and the treatment should be re-evaluated.

You should carry short-acting reliever with as with every inhalation therapy, to paradoxical bronchospasm.

FORBEMIX in the treatment of Chronic Obstructive Pulmonary Disease (COPD);

FORBEMIX should be used 2 puffs twice a day, total 4 puffs in adults aged 18 and older and elders.

**Maximum daily dose is 8 puffs for FORBEMIX.**

**Usage in Children:**

It is not recommended to use in adolescents and children under 18 years of age.

**Usage in Elderly:**

There is no special use in the elderly.

**At-risk patients:**

**FORBEMIX 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 FORBEMIX you should take for your asthma.**

**Method of administration:**

The use of the inhalation device should be shown to you by your doctor or other medical personnel. Your doctor should check how you use the aerosol for inhalation from time to time.

To control your illness, you should use the inhaled aerosol regularly and as prescribed for you.

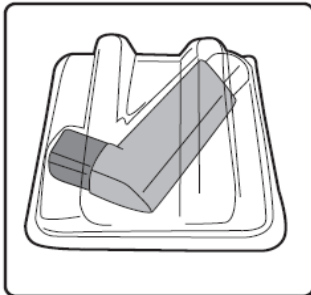
The medicine is located in a pressurized tube inside the plastic body, including the mouthpiece.

You should rinse their mouths with water after using the prescribed dose to minimize the risk of infection in oropharyngeal Candida.

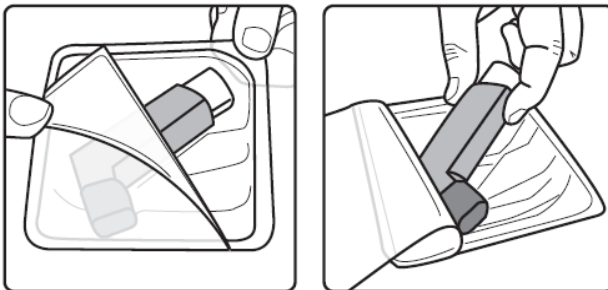
Detailed information on use is available in the leaflet for use. For the correct use of the inhalation device, carefully follow the instructions given below.

**Instructions for correct use of inhalation device:**

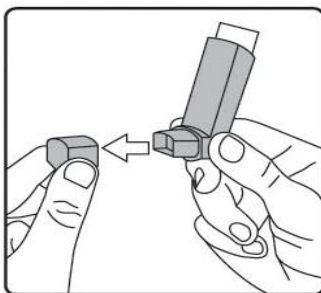
Inhaler device which is launched in the cardboard within the protective packaging for safety purposes.



Please take out your device from the package before using as shown at figure.



Testing the inhalation spray:



Before the first use, patients should take out the mouthpiece cover squeezing gently from the sides of the cover, shake the inhalation spray well and the thumb should be held between the fingers and the thumb between the fingers as it will be at the base of the inhalation spray under the mouthpiece. The inhalation spray should be shaken before each spray.

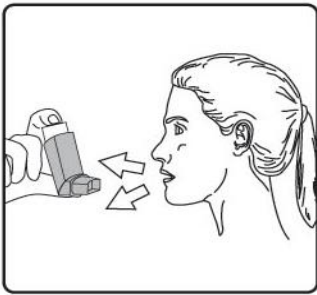
If the inhalation spray is not used for a week or longer, patients should take out the mouthpiece cover and spray twice with the inhalation spray.

When you use your inhalation spray, stand upright on your seat or standing.

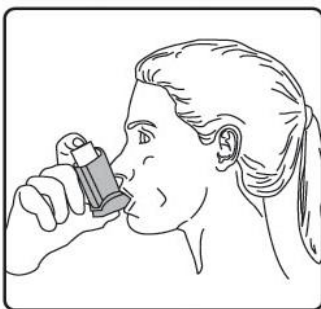
1. Take out the mouthpiece cover as shown in the first picture. Check inside and outside to make sure the cover is clean.
2. Thoroughly shake your inhalation spray before each use.



3. Keep your inhalation spray upright so that your thumb is under your mouthpiece and on the base of the inhalation spray.

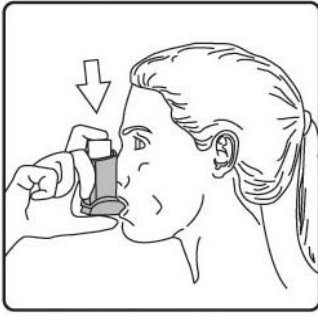


4. Put the mouthpiece between your teeth and close your lips tightly.

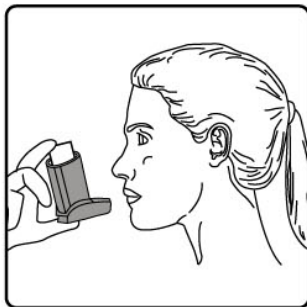


5. Breathe from your mouth slowly and deeply and press the top of your inhalation spray to empty one puff dose simultaneously.





6. Hold your breath about 10 seconds or as easily as you can, and remove the mouthpiece from your mouth and pull your fingertip from the top of your inhalation spray. Breathe out slowly from your mouth. Avoid breathing out into the inhaler.



7. Wait for about half an hour between each puff drug intake and then repeat the 2-6<sup>th</sup> steps.

8. Then, rinse your mouth with water and spit. Doing so is important to help prevent canker formation and aphonia.

9. After use, close the cover immediately to protect it from dust. When the mouthpiece cover is correctly positioned, it will fit in place. If not, turn the mouthpiece cover in the other direction. Do not apply too much force.

Patients should not perform steps 4, 5 and 6 quickly. It is important that patients begin to breathe as slowly as possible immediately before activating the inhalation spray. Patients should practice for the first few applications in front of the mirror.

If the patients see that they have steam from the top of the inhalation spray or from the mouths, they should restart the application from the second step.

### **Cleaning the inhalation spray**

Clean your inhalation spray at least once a week.

1. Remove the mouthpiece cover.

2. Do not remove the tube from the plastic body.
3. Wipe the inside and outside of the mouthpiece and the plastic body with a dry cloth.
4. Place the mouthpiece cover correctly. Do not apply too much force to place the cover.

The dose given in this leaflet is related to the inhalation of FORBEMIX using a standard inhaler. There is not enough data available for the use of FORBEMIX with a different container. If it is to be used with a different reservoir, the dose may need to be adjusted.

**Different age groups:**

**Usage in Children:**

It is not recommended to use in adolescents and children under 18 years of age.

**Usage in Elderly:**

There is no special use in the elderly.

**Special usage conditions**

**Kidney / Liver failure:**

There are no data on the use of FORBEMIX in patients with renal and liver failure.

*If you have an impression that the effect of FORBEMIX is too strong or weak, talk to your doctor or pharmacist.*

**If you use more FORBEMIX than you should:**

*If you have used more FORBEMIX than you should, talk to a doctor or pharmacist.*

- 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.
- Taking too much beclometasone dipropionate can lead to short-term problems with your adrenal glands. This will get better within a few days.

**If you forget to use FORBEMIX:**

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 FORBEOFIX:**

Do not lower the dose or stop using the medication. Consult your doctor.

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

**If your breathing gets worse:**

If you develop **worsening shortness of breath or wheezing** (breathing with an audible whistling sound), straight after inhaling your medicine, stop using FORBEOFIX 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.

**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 FORBEOFIX as reliever inhaler more frequently) or if your “reliever” inhaler or FORBEOFIX does not improve your symptoms, see your doctor immediately. Your asthma may be getting worse and your doctor may need to increase your dose of FORBEOFIX or prescribe alternative treatment.

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

**4. Possible side effects**

As with all medicines, there may be side effects in people who are sensitive to the substances in the content of FORBEOFIX.

**Side effects are listed in the following categories:**

Very common: at least 1 out of 10 patients can be seen.

Common: less than one in 10 patients, but more than one in 100 patients can be seen.

Non-common: less than one in 100 patients, but more than one in 1,000 patients can be seen.

Rarely: less than one in 1,000 patients, but more than one in 10,000 patients can be seen.

Very rare: less than one in 10,000 patients can be seen (including isolated cases).

The frequency is Unknown: it can not be determined with the available data from very few patients.

**If any of the following occurs, stop using FORBEFIX and report it to your doctor or contact your nearest hospital emergency department IMMEDIATELY.**

An electrocardiogram (EKG) changes in the electrocardiogram and an elongation in the qtc interval (a wave in electrocardiogram seen as a symptom of disease), increased blood collection, tremor, asthma attack.

These are all very serious side effects. If you develop asthma attacks, you have severe allergies to FORBEFIX. You may need urgent medical attention or hospitalization.

For cases of emergency response, except for allergic side effects; If you have any of these symptoms, you may need to be hospitalized for emergency medical attention.

Very serious side effect are rare.

#### **Common (less than 1 in 10 people)**

- Headache
- Dysphonia
- Pain in the throat, burning and feeling of dryness (pharyngitis)
- Pneumoniae in COPD patients (infections in lungs)

#### **Uncommon (seen in less than 1 person in 100 people)**

- Palpitations
- Disorders of heart rhythm
- Unusual fast heartbeat
- Abnormal electrical signal production in the heart (prolongation of QTc interval) changes in electrocardiogram (ECG) and elongation in the corrected QTc interval according to heart rate Excessive bleeding in tissue (hyperemia)
- Shake
- Symptoms of influenza
- Thrush in the mouth and throat

- Vaginal yeast infection
- Sinus inflammation
- Allergic rhinitis
- Itching, rash, skin water
- Sore throat
- Coughing
- Productive cough
- Asthma attacks
- Nausea
- Taste disorders
- Burning lips
- Dry mouth
- Difficulty swallowing
- Indigestion
- Diarrhea
- Muscle pain and cramps
- Hot flashes
- Unrest
- Dizziness, lightheadedness
- Changes in blood values
- Decreased white blood cells
- Decreased blood potassium levels
- Elevation in blood sugar
- Increase in blood insulin, ketones and free fatty acids
- Allergic eczema (dermatitis)
- Inflammation of the eustachian tube in the ear

**Rare (less than 1 in 1,000 people)**

- Angina pectoris (pain in the chest)
- Feeling of fullness in the chest
- Heart beat tab (ventricular contraction in the heart too early)
- Increased or decreased blood pressure
- Inflammation in the kidney
- Water in the skin
- Hives
- Irregular breathing

**Very rare (seen in less than 1 person in 10,000 people)**

- Irregular heartbeat
- Shortness of breath
- Worsening of asthma
- Abnormal behavior
- Sleep disorders and hallucinations
- Decreased blood platelets
- Hand and foot swelling
- Redness of the skin (erythema)
- Glaucoma
- Cataract
- Hypersensitivity, including sudden swelling and narrowing of the mouth, throat, and pharynx due to allergies
- Adrenal insufficiency
- Growth retardation in children and adolescent
- Water collection in the body overall
- Decreased bone density (bone thinning)

Tell your doctor if you experience any of the following symptoms while using beclomethasone dipropionate: These symptoms may be signs of lung infection:

- Fever or chills
- Increase in mucus production, change in mucus color
- Increased cough or increase in shortness of breath

*If you encounter any side effects not mentioned in these instructions for use, please inform your doctor or pharmacist.*

## **5.How to store FORBEFIX**

*Store FORBEFIX in places where it cannot be seen, cannot be accessed by children and in its packaging.*

The aerosol box should not be punctured, even if it is empty, it should not be broken and should be kept away from fire.

Store at room temperature below 25°C. It should be protected from direct sunlight and freezing.

### **Use in accordance with the expiration date.**

*Do not use FORBEFIX after the expiration date on the packaging.*

Do not use FORBEFIX if you notice any defects in the product and / or packaging.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

**Marketing Authorization Holder:** Neutec İnhaler İlaç San. ve Tic. A.Ş  
Arifiye / SAKARYA / TURKEY  
Phone : +90 850 201 23 23  
Fax : +90 212 481 61 11  
e-mail: info@neutecinhaler.com

**Manufacture Site:** Neutec İnhaler İlaç San. ve Tic. A.Ş.  
Arifiye / SAKARYA / TURKEY