Package leaflet: Information for the user

BIBECFO 100/6 micrograms per 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 symptoms and signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What BIBECFO is and what it is used for

BIBECFO 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
BIBECFO 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
BIBECFO 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 BIBECFO

Do not use BIBECFO:

- 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 BIBECFO:

- 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, a fast pulse rate or palpitations or 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 phaeochromocytoma).
- If you are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking BIBECFO 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 BIBECFO. If you have or had any medical problems or any allergies or if you are not sure as to whether you can use BIBECFO talk to your doctor, asthma nurse or pharmacist before using this medicine.

Treatment with a beta-2-agonist like the formoterol contained in BIBECFO 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 BIBECFO, 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 BIBECFO 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
BIBECFO should not be used in children and adolescent less than 18 years old, until further data become available.

Other medicines and BIBECFO
Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines including medicines for asthma and COPD or any medicines obtained without a prescription.

Some medicines may increase the effects of BIBECFO 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
Beta blockers such as atenolol, propranolol and sotalol are used to treat a number of conditions including high blood pressure and heart conditions such as abnormal heart rhythms and heart failure; timolol is used to treat glaucoma. If you need to use beta blockers, and including beta blockers in 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 BIBECFO 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 and breastfeeding
There are no clinical data on the use of BIBECFO during pregnancy.

BIBECFO must not be used if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
BIBECFO is unlikely to affect your ability to drive and use machines. However, if you experience side effects such as dizziness and/or trembling, your ability to drive or operate machinery may be affected.

BIBECFO contains alcohol
This medicine contains 7 mg of alcohol (ethanol) in each actuation which is equivalent to 0.194 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 BIBECFO

BIBECFO is for inhalation use. BIBECFO should be inhaled via your mouth into your lungs.

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.

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

BIBECFO can be prescribed by your doctor in two different ways:
a) Use BIBECFO 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 BIBECFO every day to treat your asthma and also use this medicine to treat sudden worsening of your asthma symptoms, such as shortness of breath, wheezing and cough.

a) **Using BIBECFO together with a separate "reliever":**
Adults and the elderly:
The recommended dose of this medicine 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 BIBECFO 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 this medicine 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 BIBECFO "reliever" puffs per day.

The maximum daily dose of BIBECFO as your only asthma inhaler 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 BIBECFO in people with liver or kidney problems.

BIBECFO 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 BIBECFO 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.

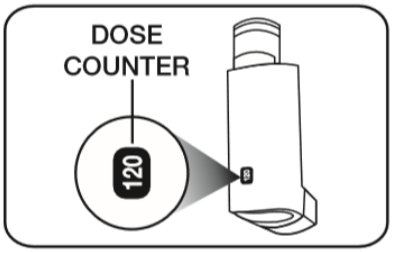
Method of administration

BIBECFO 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 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. If you are testing your inhaler for the first time, the counter should read 120.



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

Before you start inhaling, check the dose counter: any number between “1” and “120” shows that there are doses left. If the dose counter shows “0” there are no doses left – dispose of your inhaler and get a new one.

1. Remove the protective cap from the mouthpiece and check that the mouthpiece is clean and free from dust and dirt or any other foreign objects.
2. Breathe out as slowly and deeply as possible.
3. Hold the canister vertically with its body upwards and put 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.
5. Hold your breath for as long as possible and, finally, remove the inhaler from your mouth and breathe out slowly. Do not Breathe into the inhaler.

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

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

After use, close with the protective cap and check the dose counter.

You should get a replacement when the counter 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.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that BIBECFO 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.

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.

If you think the effect of BIBECFO 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.

If you use more BIBECFO than you should
- Taking more formoterol than you should 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 carry out some blood tests to check your serum cortisol levels.

Tell your doctor if you have any of these symptoms.

If you forget to use BIBECFO
Do not take a double dose to make up for a forgotten dose. 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.

If you stop using BIBECFO
Do not lower the dose or stop using the medication. Even if you are feeling better, do not stop taking BIBECFO or lower the dose. If you want to do this, talk to your doctor. It is very important for you to use this medicine 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 BIBECFO 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 BIBECFO as reliever inhaler more frequently) or if your "reliever" inhaler or BIBECFO 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 BIBECFO or prescribe alternative treatment.

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

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 this medicine and this is known as **paradoxical bronchospasm**. If this occurs you should **STOP using BIBECFO immediately** and use your q**uick-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

Pneumonia in COPD patients: Tell your doctor if you have any of the following while taking BIBECFO 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)
- unusual fast heartbeat and disorders of heart rhythm
- some changes in the electrocardiogram (ECG)
- asthma attack
- trembling
- restlessness
- dizziness
- palpitations
- flu symptoms
- fungal infections of the vagina
- inflammation of the sinuses

- inflammation of the ear
- throat irritation
- cough and productive cough
- nausea
- abnormal or impaired sense of taste
- burning of the lips
- dry mouth
- swallowing difficulties
- indigestion
- upset stomach
- diarrhoea
- pain in the muscles and muscle cramp
- reddening of the face
- excessive sweating
- increased blood flow to some tissue in the body
- rhinitis

Alterations of some constituents of the blood:
- fall in the number of white blood cells
- increase in the number of blood platelets
- a 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
- nettle rash or hives

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 heart beat.

Rare (may affect up to 1 in 1,000 people)
- tightness in the chest
- sensation of a missed heartbeat
- increase 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)
- worsening of asthma
- shortness of breath
- a fall in the number of blood platelets
- swelling of the hands and feet

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 (adrenosuppression)
- increased pressure in your eyes (glaucoma)
- cataracts
- growth retardation (slowing of growth in children and adolescents)
- decrease in bone mineral density (thinning of the bones)

Not known (frequency cannot be estimated from the available data)
- sleeping problems,
- depression or feeling worried
- restless
- nervousness

- over-excited or irritable.

These events are more likely to occur in children.
- Blurred vision

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 Yellow Card Scheme, Website: https://yellowcard.mhra.gov.uk/, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BIBECFO

- Keep this medicine out of the sight and reach of children.
- Before use: store the inhaler in a refrigerator (at 2-8°C).
- After first use: do not store the inhaler above 25 °C for a maximum of three months.
- 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.
- Do not freeze.
- 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.
- Medicines should not be disposed of via wastewater or household waste. Return all used, partially used and unused inhalers to your pharmacist to be disposed of. These measures will help to protect the environment.

6. Contents of the pack and other information

What BIBECFO contains
- The active substances are beclometasone dipropionate, 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 ingredient are ethanol anhydrous, hydrochloric acid and the CFC-free propellant - norflurane (HFA -134a). To help protect the environment, the inhaler contains the CFC-free propellant, HFA-134a, which replaces completely the chlorofluorocarbon (CFC) propellants present in some other inhalers and appears to have a less damaging effect on the ozone layer. This medicine does not contain CFCs.

What BIBECFO looks like and contents of the pack
BIBECFO is a pressurised solution contained in an aluminium canister with a metering valve, fitted into a plastic actuator (white) incorporating a mouthpiece and fitted with a dose counter, with a dustcap (mauve).

Each pack contains:

1 pressurised container which provides 120 actuations or
2 pressurised containers which provide 120 actuations each

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Marketing Authorisation Holder

Cipla (EU) Limited
Dixcart House, Addlestone Road,
Bourne Business Park, Addlestone,
KT15 2LE, United Kingdom

Manufacturer

Cipla (EU) Limited
Dixcart House, Addlestone Road,
Bourne Business Park, Addlestone,
KT15 2LE, United Kingdom

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