

PACKAGE LEAFLET: INFORMATION FOR THE USER

Beclometasone/formoterol

100 micrograms /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 or pharmacist
- 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 or pharmacist This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Beclometasone/formoterol is and what it is used for**
- 2. What you need to know before you use Beclometasone/formoterol**
- 3. How to use Beclometasone/formoterol**
- 4. Possible side effects**
- 5. How to store Beclometasone/formoterol**
- 6. Contents of the pack and other information**

1. What Beclometasone/formoterol is and what it is used for

Beclometasone/formoterol 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

Beclometasone/formoterol 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

Beclometasone/formoterol 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.

Beclometasone/formoterol is for the use in adults.

2. What you need to know before you use Beclometasone/formoterol

Do not use Beclometasone/formoterol:

- 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 or pharmacist before using Beclometasone/formoterol:

- 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 pheochromocytoma).
- If you are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking Beclometasone/formoterol 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 Beclometasone/formoterol.

If you have or had any medical problems or any allergies or if you are not sure as to whether you can use Beclometasone/formoterol talk to your doctor or pharmacist before using this medicine.

Treatment with a beta-2-agonist like the formoterol contained in Beclometasone/formoterol 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 Beclometasone/formoterol, 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 Beclometasone/formoterol 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

Beclometasone/formoterol should not be used in children and adolescent less than 18 years old, until further data become available.

Other medicines and Beclometasone/formoterol:

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because Beclometasone/formoterol may affect the way some other medicines work. Also, some medicines may affect the way Beclometasone/formoterol works.

In particular, tell your doctor<,><or> pharmacist <or nurse> if you are using any of the following medicines:

- Some medicines may increase the effects of Beclometasone/formoterol and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- Beta-blocker medicines. Beta blockers are medicines used to treat many conditions including heart problems, high blood pressure and glaucoma (increased pressure in the eyes). If you need to use beta blockers including eye drops, the effect of formoterol may be reduced or formoterol may not work at all.
- Beta adrenergic drugs (drugs 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).
- Medicines to treat symptoms of depression or mental disorders such as monoaminoxidase inhibitors (for example phenelzine and isocarboxazid), tricyclic antidepressants (for example amitriptyline and imipramine), phenothiazines.
- Medicines to treat Parkinson's Disease (L-dopa).
- Medicines to treat an underactive thyroid gland (L-thyroxine).
- Medicines containing oxytocin (which causes uterine contraction).
- Medicines to treat mental disorders such as monoaminoxidase inhibitors (MAOIs), including drugs with similar properties like furazolidone and procarbazine.
- Medicines to treat heart disease (digoxin).
- Other medicines used to treat asthma (theophylline, aminophylline or steroids).
- Diuretics (water tablets).

Also tell your doctor if you are going to have a general anaesthetic for an operation or for dental work.

Pregnancy, breast-feeding and fertility

There are no clinical data on the use of Beclometasone/formoterol during pregnancy.

Do not take Beclometasone/formoterol if you are pregnant, think you may be pregnant or are planning to have a baby, or if you are breast-feeding, unless you are advised to do so by your doctor.

Driving and using machines

Beclometasone/formoterol is unlikely to affect your ability to drive and use machines.

Beclometasone/formoterol contains alcohol

This medicine 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 of this medicine is equivalent to less than 1 ml of beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Beclometasone/formoterol

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 Beclometasone/formoterol. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms.

Beclometasone/formoterol can be prescribed by your doctor in two different ways:

- a) **Use Beclometasone/formoterol 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**

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) **Use Beclometasone/formoterol every day to treat your asthma and also use Beclometasone/formoterol to treat sudden worsening of your asthma symptoms, such as shortness of breath, wheezing and cough**

Adults and the elderly:

The recommended dose is one puff in the morning and one puff in the evening.

You should also use Beclometasone/formoterol 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 Beclometasone/formoterol “reliever” puffs per day.

The maximum daily dose of Beclometasone/formoterol 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 Beclometasone/formoterol in people with liver or kidney problems.

Beclometasone/formoterol 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 Beclometasone/formoterol 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 inhaling your medicine, stop using Beclometasone/formoterol 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 Beclometasone/formoterol as reliever inhaler more frequently) or if your “reliever” inhaler or Beclometasone/formoterol 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 Beclometasone/formoterol or prescribe alternative treatment.

Method of administration:

Beclometasone/formoterol is for inhalation use.

This medicine is contained in a pressurised canister in a plastic casing with a mouthpiece. There is a dose counter for the 120 doses actuations and a dose indicator for the 180 actuations on the back of the inhaler, which tells you how many doses are left.

For the pack size containing 120 actuations, 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.

For the pack size containing 180 actuations, the dose indicator will show the approximate number of actuations (sprays) remaining in the canister. The dose-indicator window displays the number of sprays left in the inhaler in units of twenty (e.g., 180, 120, 100, 80, etc). When 20 actuations remain, so that the display shows the number 20 it indicates that the canister is closer to its end of life.

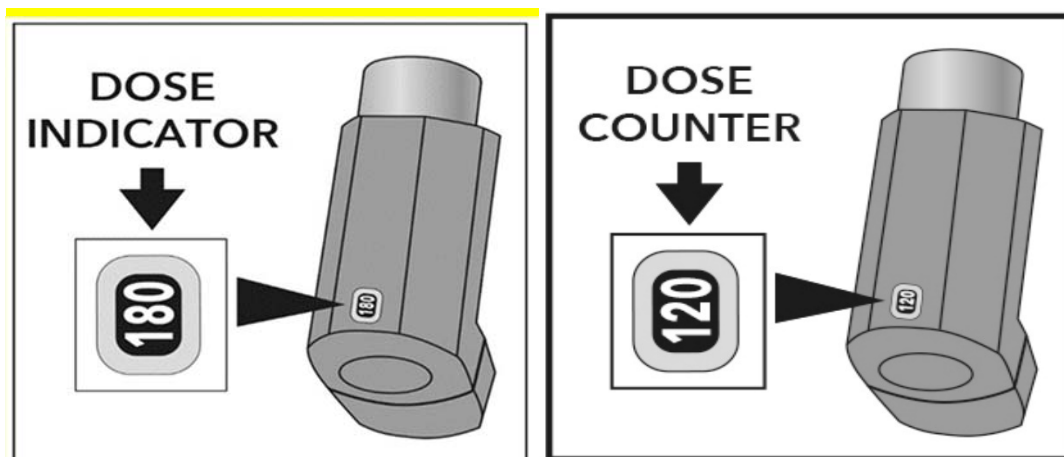
When 180 actuations have been discharged, the display shows the number 0.

The indicator will stop moving at “0”.

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.

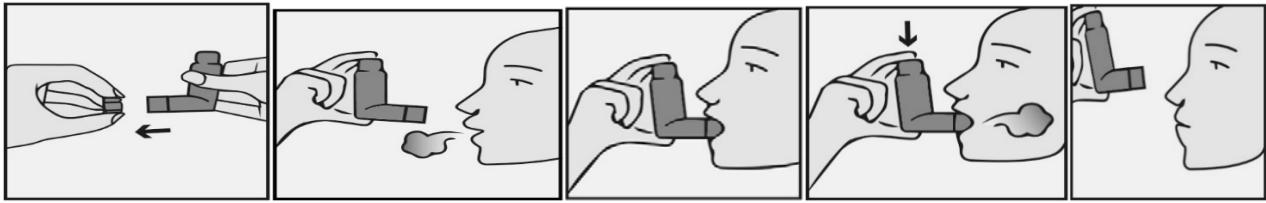
- Remove the protective cap from the mouthpiece.
- Hold your inhaler upright with the mouthpiece at the bottom.
- Direct the mouthpiece away from yourself and firmly depress the canister to release one puff.
- If you have not used the inhaler for 14 days or more firmly depress the canister once to release one puff.
- For the pack size containing 120 actuations check the dose counter. If you are testing your inhaler for the first time, the counter should read 120.
- For the pack size containing 180 actuations check the dose indicator. If you are testing your inhaler for the first time, the counter should read 180.



How to use your inhaler

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

Before you start inhaling, check the dose counter or dose indicator that show how many doses are left. If the dose counter or dose indicator show “0” there are no doses left – dispose of your inhaler and get a new one.



1)

2)

3)

4)

5)

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 (Picture 1).
2. Breathe out as slowly and deeply as possible (Picture 2).
3. Hold the canister vertically with its body upwards and put your lips around the mouthpiece. Do not bite the mouthpiece (Picture 3).
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. (Picture 4)
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 (Picture 5).

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 for the pack size containing 120 doses and the dose indicator for the pack size containing 180 actuations.

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.

When to replace your inhaler

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

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that Beclometasone/formoterol 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 Beclometasone/formoterol 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<,> <or> 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 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 Beclometasone/formoterol 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 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 Beclometasone/formoterol:

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 Beclometasone/formoterol:

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

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

4. Possible side effects

Like all medicines, 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 Beclometasone/formoterol and this is known as **paradoxical bronchospasm**. If this occurs, you should **STOP using Beclometasone/formoterol 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 Beclometasone/formoterol 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, unusually fast heart beat and heart rhythm disorders
- some changes in the electrocardiogram (ECG)
- 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

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):

- chest tightness
- missed heartbeat (caused by premature contraction of the heart's ventricles)
- decrease in blood pressure
- increase 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

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

Not known (frequency cannot be estimated from the available data):

- sleeping problems
- depression or anxiety
- nervousness
- feeling over-excited or irritable.

These events are more likely to occur in children but the frequency is not known.

- Blurred vision

Reporting of side effects

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. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Beclometasone/formoterol

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

Single pack containing one actuator with 120 doses or 180 doses

For pharmacist:

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

Enter the date of dispensing to the patient on the sticky label on the pack and stick the label on the inhaler. Ensure that there is a period of at least 3 months between the date of dispensing and the expiry date printed on the pack.

For patients:

Do not store the inhaler above 25 °C.

Do not use Beclometasone/formoterol 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.

Double or triple packs containing two or three actuators of 120 doses

Before use: store the inhalers in a refrigerator (at 2-8°C).

After first use: do not store the inhalers above 25 °C for a maximum of three months.

Every time you start to use an inhaler, enter the date of first use on the sticky label on the pack and stick the label on the inhalers. The inhalers should not be used after 3 months from the first use and never use it 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 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.

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

6. Contents of the pack and other information

What Beclometasone/formoterol 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 ingredients are: ethanol anhydrous, hydrochloric acid concentrated and norflurane (HFA - 134a).

This medicine contains fluorinated greenhouse gases.

Each inhaler of 120 actuation contains 8,15 g of HFC-134a corresponding to 0.012 tonne CO₂ equivalent (global warming potential GWP = 1, 430).

Each inhaler of 180 actuation contains 11,2 g of HFC-134a corresponding to 0.016 tonne CO₂ equivalent (global warming potential GWP = 1, 430).

What Beclometasone/formoterol looks like and contents of the pack:

Beclometasone/formoterol is a pressurised inhalation solution contained in an aluminium canister with a metering valve, fitted in a white plastic actuator which incorporates a dose counter (120 actuations pack) or a dose indicator (180 actuations pack) with a pink plastic protective cap.

Each pack contains:

- 1 pressurised container (which provides 120 actuations) (puffs) or
- 2 pressurised containers (which provide 120 actuations) each or
- 3 pressurised containers (which provide 120 actuations) each or
- 1 pressurised container (which provides 180 actuations)

Not all pack sizes may be marketed.

Marketing authorisation holder and Manufacturer:

Marketing authorisation holder

<[to be completed nationally]>

Manufacturer:

Genetic S.p.A.

Contrada Canfora

84084 Fisciano

Italy

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

Country	Proposed Product Name
Austria	Beclometason/Formoterol Genetic 100 mikrogramm /6 mikrogramm/Sprühstoß Druckgasinhalation, Lösung
	Beclometason/Formoterol Genetic 200 mikrogramm /6 mikrogramm/Sprühstoß Druckgasinhalation, Lösung
Belgium	Beclometasone/Formoterol Genetic 100 microgram /6 microgram/dosis aërosol, oplossing Beclometasone/Formoterol Genetic 200 microgram /6 microgram/dosis aërosol, oplossing

Luxembourg	Beclometasone/Formoterol Genetic 100 microgrammes /6 microgrammes/dose, solution pour inhalation en flacon pressurisé
	Beclometasone/Formoterol Genetic 200 microgrammes /6 microgrammes/dose, solution pour inhalation en flacon pressurisé
Germany	Beclometason/Formoterol Genetic 100 Mikrogramm/6 Mikrogramm pro Inhalation Druckgasinhalation, Lösung
	Beclometason/Formoterol Genetic 200 Mikrogramm/6 Mikrogramm pro Inhalation Druckgasinhalation, Lösung
Netherlands	Beclometason/Formoterol Allgen 100 microgram /6 microgram/dosis, aërosol, oplossing
	Beclometason/Formoterol Allgen 200 microgram/6 microgram/dosis, aërosol, oplossing
Estonia	Beclametason/Formoterol Genetic
France	BÉCLOMÉTASONE/FORMOTÉROL BIOGARAN 100 microgrammes /6 microgrammes/dose, solution pour inhalation en flacon pressurisé
	BÉCLOMÉTASONE/FORMOTÉROL BIOGARAN 200 microgrammes /6 microgrammes/dose, solution pour inhalation en flacon pressurisé
Lithuania	Beclometason/Formoterol Genetic 100 mikrogramai /6 mikrogramai/išpurškime suslėgtasis įkvepiamasis tirpalas
	Beclometason/Formoterol Genetic 200 mikrogramai /6 mikrogramai/išpurškime suslėgtasis įkvepiamasis tirpalas
Latvia	Beclometasone/Formoterol Genetic 100 mikrogrami/6 mikrogrami izsmidzinājumā aerosols inhalācijām, zem spiediena, šķīdums
	Beclometasone/Formoterol Genetic 200 mikrogrami/6 mikrogrami izsmidzinājumā aerosols inhalācijām, zem spiediena, šķīdums
Romania	Beclometazonă/Formoterol Genetic 100 micrograme /6 micrograme pe doză, soluție de inhalat presurizată
	Beclometazonă /Formoterol Genetic 200 micrograme /6 micrograme pe doză, soluție de inhalat presurizată
Slovakia	Beklometasón-formoterol Genetic 100 mikrogramov /6 mikrogramov/dávka
	Beklometasón-formoterol Genetic 200 mikrogramov /12 mikrogramov/dávka

Italy	Beclometasone e Formoterolo Genetic
Portugal	Beclometasona Formoterol Genetic 100 mcg/6 mcg Solução pressurizada para inalação
	Beclometasona Formoterol Genetic 200 mcg/6 mcg Solução pressurizada para inalação
Spain	Beclometasona Formoterol Genetic 100 microgramos/6 microgramos/pulsación Solución para inhalación en envase a presión
	Beclometasona Formoterol Genetic 200 microgramos/6 microgramos/pulsación Solución para inhalación en envase a presión
Greek	BREAIR
Poland	AEROX
Hungary	Beclometasone formoterol Genetic 100 mcg /6 mcg túlnyomásos inhalációs oldat
	Beclometasone formoterol Genetic 200 mcg /6 mcg túlnyomásos inhalációs oldat
Bulgaria	Беклометазон формотерол Genetic 100 микрограма /6 микрограма/доза,разтвор под налягане за инхалация
	Беклометазон формотерол Genetic 200 микрограма /6 микрограма/доза,разтвор под налягане за инхалация
Czech Republic	Beklometason/Formoterol Genetic
Slovenia	Beklometazondipropionat Formoterolijev Genetic 100 mikrogramov /6 mikrogramov na sprožitev inhalacijska raztopina pod tlakom
	Beklometazondipropionat Formoterolijev Genetic 200 mikrogramov /6 mikrogramov na sprožitev inhalacijska raztopina pod tlakom
Ireland	Beclometasone/formoterol 100 microgram/60 microgram per actuation pressurised inhalation solution
	Beclometasone/formoterol 200 microgram/60 microgram per actuation pressurised inhalation solution
Croatia	Beklometazondipropionat/formoterolfumarat dihidrat Genetic 100 mikrograma /6 mikrograma po potisku, stlačeni inhalat, otopina
	Beklometazondipropionat/formoterolfumarat dihidrath Genetic 200 mikrograma /6 mikrograma po potisku, stlačeni inhalat, otopina

Malta	<p>Beclometasone formoterol Genetic 100 microgram/6 microgram per actuation pressurized inhalation solution</p> <p>Beclometasone formoterol Genetic 200 microgram/6 microgram per actuation pressurized inhalation solution</p>
Cyprus	<p>Beclometasone formoterol Genetic 100 microgram/6 microgram per actuation pressurized inhalation solution</p> <p>Beclometasone formoterol Genetic 200 microgram/6 microgram per actuation pressurized inhalation solution</p>

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