

Reason for Update: Type IA – Deletion of Chiesi site and removal of ‘ La Madeleine’ from Evreux address
Market: IE
Agency Approval Date: 31/03/2021 (Type IA submission)
Text Date: 26/02/2021
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Package leaflet: Information for the user

Becotide Evohaler 50, 100 and 250 micrograms Pressurised Inhalation Solution (Beclometasone dipropionate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor 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 Becotide Evohaler is and what it is used for
2. What you need to know before you use Becotide Evohaler
3. How to use Becotide Evohaler
4. Possible side effects
5. How to store Becotide Evohaler
6. Contents of the pack and other information.

1. What Becotide Evohaler is and what it is used for

Becotide contains the active substance beclometasone dipropionate. Beclometasone dipropionate belongs to a group of medicines called corticosteroids (often just called steroids). A very small dose of steroid is needed when it is inhaled. This is because it is inhaled straight to your lungs.

Becotide works by reducing swelling and irritation in the lungs. It has what is called an ‘anti-inflammatory action’.

Becotide helps to prevent asthma attacks in people who need regular treatment. This is why it is sometimes called a ‘preventer’. It needs to be used regularly, every day.

Becotide will not help treat sudden asthma attacks where you feel breathless.

- A different medicine is used for treating sudden attacks (called a ‘reliever’).
- If you have more than one medicine, be careful not to confuse them.

Becotide is supplied to you in an inhaler. You breathe the medicine directly into your lungs.

Becotide contains norflurane. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Becotide. This will make no difference to how your medicine works. It also contains small amounts of ethanol (alcohol) and glycerol. At the usual dose, these amounts are so small that they should not cause any problems.

2. What you need to know before you use Becotide Evohaler

Do not use Becotide:

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

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Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Becotide if:

- you have ever been treated for tuberculosis (TB).
- you have ever had thrush (candidiasis) in your mouth.
- you are using Becotide at the same time as taking steroid tablets or injections. Also, if you have just finished taking steroid tablets or injections. In both cases, you should carry a steroid warning card until your doctor tells you not to carry one.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Becotide.

If your breathing or wheezing gets worse straight after using Becotide Evohaler, **stop using it and tell your doctor immediately.**

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

Other medicines and Becotide Evohaler

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go into hospital.

Some medicines may increase the effects of Becotide Evohaler and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If you are taking metronidazole (an antibiotic) or disulfiram (a treatment for alcohol dependency), please speak with your doctor before taking Becotide Evohaler.

Using Becotide with food and drink

You can use Becotide at any time of day, with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Becotide is not likely to affect you being able to drive or use any tools or machines.

Becotide Evohaler contains ethanol.

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

3. How to use Becotide Evohaler

Becotide come in three different strengths. Your doctor will have decided which strength you need. Always take this medicine exactly as your doctor has told you. The label on it will usually tell you how much to take and how often. Check with your doctor or pharmacist if you are not sure. Do not change the amount of medicine you take, unless your doctor has told you to.

Using this medicine

- Becotide is for inhalation by mouth only.
- Instructions on how to use the inhaler are given as a step-by-step guide below.
- It takes a few days for this medicine to work and it is very important that you use it regularly.
- **Do not** stop using it even if you feel better, unless told to do so by your doctor.
- **Do not** use more than you are told.
- **Do not** use this medicine to treat a sudden attack of breathlessness – it will not help you. You should use a quick-acting reliever inhaler (e.g. Ventolin) for this purpose.

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Adults and adolescents aged 12 years and over

- The usual dose is 200 to 2,000 micrograms a day, in divided doses.
- The most an adult should take is 2,000 micrograms a day.
- There is no need to adjust the dose in elderly patients or patients with liver or kidney problems.

Children over 4 years

- The usual dose is 200 to 400 micrograms a day, in divided doses
- The most a child should take is 400 micrograms a day.
- It is recommended that children being treated with steroids, including Becotide have their height checked regularly by their doctor.

If you are using high doses of an inhaled steroid for a long time you may sometimes need extra steroids for example during stressful circumstances such as a road traffic accident or before an operation. Your doctor may decide to give you extra steroid medicines during this time.

Instructions for use

Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the Becotide inhaler properly or as prescribed, may mean that the medicine will not help you as it should.

The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.

Testing your inhaler



1. When using your inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

2. To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release a puff into the air. If you have not used the inhaler for three days or more, release one puff of medicine into the air.

Using your inhaler

It is important to start to breathe in as slowly as possible just before using your inhaler.

1. Stand or sit upright when using your inhaler.
2. Remove the mouthpiece cover (as shown in the first picture) . Check inside and outside to make sure that the mouthpiece is clean and free of objects.

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3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable.



5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



6. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.



7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.

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8. Wait about half a minute between taking each puff of medicine and then repeat steps 3 to 7.

9. After use always replace the mouthpiece cover immediately to keep out dust. Replace the cover by firmly pushing and snapping the cap into position.

Practise in front of a mirror for the first few times. If you see a ‘mist’ coming from the top of your inhaler or the sides of your mouth you should start again.

If you or your child find it difficult to use the Evohaler, a large volume spacer device may improve the treatment with Becotide. Talk to your doctor, nurse or pharmacist.

The Babyhaler spacer device is available for use in young children.

People with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. If this does not help, a special device called a Haleraid may make it easier. Talk to your doctor, nurse or pharmacist.

Cleaning your inhaler

To stop your inhaler blocking up, it is important to clean it at least once a week.

To clean your inhaler:

- Pull the metal canister out of the plastic casing of the inhaler and remove mouthpiece cover.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a damp cloth.
- Leave to dry in a warm place. Avoid excessive heat.
- Replace the canister and mouthpiece cover.

DO NOT PUT THE METAL CANISTER IN WATER.

If you use more Becotide than you should

If you use more than you should, **talk to your doctor as soon as possible.**

It is important that you take your dose as stated on the pharmacist’s label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you forget to use Becotide Evohaler

If you forget to use your inhaler, take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

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.

If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away. You may need urgent medical treatment.

- allergic reactions (may affect up to 1 in 100 people) – the signs include skin rashes, redness, itching or weals like nettle rash or hives
- severe allergic reactions (may affect up to 1 in 10,000 people) - the signs include swelling of your face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed and collapse
- your breathing or wheezing gets worse straight after using your inhaler.

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Talk to your doctor as soon as possible if:

- after 7 days of using Becotide your shortness of breath or wheezing does not get better, or gets worse.

Other side effects include:

Very common (may affect more than 1 in 10 people)

- thrush in the mouth and throat

Common (may affect up to 1 in 10 people)

- sore throat
- hoarseness of voice

Problems with your mouth and throat can be reduced by doing certain things straight after inhaling your dose. These are brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your doctor if you have these problems with your mouth or throat, but do not stop treatment unless you are told to.

Very rare (may affect up to 1 in 10,000 people)

- sleeping problems or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children
- the way steroids are produced by your body may be affected when using Becotide. This is more likely to happen if you use high doses for a long period of time. This can cause:
 - children and young people to grow more slowly.
 - something called ‘Cushing’s syndrome’. This happens when you have too much steroid in your body and it can cause thinning of your bones and eye problems (such as cataracts and glaucoma).

Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

Frequency not known, but may also occur

- Depression or aggression. These effects 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 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 Becotide Evohaler

- **Keep this medicine out of the sight and reach of children.**
- Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.
- Do not refrigerate or freeze.
- Protect from frost and direct sunlight.
- If the Evohaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few min before use. NEVER use anything else to warm it up.
- Do not store above 30°C.
- The metal canister contains a pressurised liquid. Do not expose the canister to temperatures higher than 50°C. Do not puncture, break or burn it even if you think it is empty.
- Do not use Becotide after the expiry date which is stated on the label and carton. The expiry date refers to the last day of the month.

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

6. Contents of the pack and other information

What Becotide contains

- The active substance is beclometasone dipropionate
- The other ingredients are norflurane (HFA 134a), ethanol (alcohol) and glycerol.

What Becotide looks like and contents of the pack

Pressurised inhalation solution. The pressurised canister contains a clear and colourless solution for inhalation.

Each puff contains 50 micrograms, 100 micrograms or 250 micrograms beclometasone dipropionate. There are 200 puffs in each canister.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24.

Manufacturer:

Glaxo Wellcome Production, Zone Industrielle No.2, 23 Rue Lavoisier, 27000 Evreux, France.

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