

Scheduling Status:

S3

BECLOREST 50 & 100, pressurised inhalation solution Micronized beclometasone dipropionate

Read all this leaflet carefully before you start using BECLOREST

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- BECLOREST has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What BECLOREST is and what it is used for:

BECLOREST contains beclometasone dipropionate, which is one of a group of medicines known as corticosteroids.

BECLOREST is used to prevent the symptoms of mild, moderate, or severe asthma, in patients who require regular treatment.

Steroids have an anti-inflammatory action reducing the swelling and irritation in the walls of the small air passages in the lungs, and so ease breathing problems.

2. What you need to know before you use BECLOREST:

Do not use BECLOREST:

- If you are hypersensitive (allergic) to beclometasone dipropionate or any of the other ingredients of BECLOREST (listed in section 6).
- If you experience a sudden attack of breathlessness.
- If you are pregnant (see “Pregnancy, breastfeeding and fertility”).

Warnings and precautions:

Special care should be taken with BECLOREST:

- If you are suffering from tuberculosis (TB) now or have suffered from it in the past.
- If you should avoid alcohol due to addiction (alcoholism), medical or other reasons, because BECLOREST contains a small amount of alcohol (see "BECLOREST contains alcohol" below).
- If your asthma seems to be getting worse. Perhaps you are wheezier and shorter of breath than usual, your 'reliever' inhaler seems to be less effective, you require more puffs from your 'reliever' inhaler than usual, or you do not seem to be getting better. Your doctor may need to increase the dose of your steroid inhaler or give you a course of steroid tablets or change your treatment altogether. If you have had an infection in your chest your doctor may prescribe a course of antibiotics.
- When transferring from steroid tablets to an inhaler you find that, even if your chest is getting better, you feel generally unwell, you develop a rash, eczema or a runny nose and sneezing (rhinitis). Do not stop treatment with your inhaler unless your doctor tells you to.

If you have been treated for a long time with high doses of inhaled steroid, you may require a course of steroid tablets or possibly a steroid injection in times of stress. For example, during admission to hospital after a serious accident, before an operation, during an acute attack of asthma or if you have a chest infection or other serious illness. Your doctor will decide if you need any extra steroid treatment and will also advise you as to how long you need to take the course of steroid tablets and how you should reduce these as you get better.

If you are using BECLOREST instead of, or as well as taking steroid tablets, or if your doctor is trying to reduce the dose of your steroid tablets, you should carry a steroid warning card until your doctor tells you that you do not need to.

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

Children and adolescents

If your child is receiving prolonged treatment with BECLOREST, your doctor should regularly monitor their height to evaluate if growth impairment occurs.

Other medicines and BECLOREST

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Disulfiram (used in the treatment of alcoholism)
- Metronidazole (used to treat infections).

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist, or other healthcare provider for advice before using BECLOREST.

The safety of BECLOREST in pregnancy has not been established. You should not use BECLOREST if you are pregnant.

Driving and using machines

It is not always possible to predict to what extent BECLOREST may interfere with your daily activities. If you experience blurred vision you should ensure that you do not engage in driving a vehicle or use machines.

BECLOREST contains alcohol

BECLOREST contains a small amount of alcohol. Each actuation (puff) from your inhaler contains about 4,32 mg of ethanol.

3. How to use BECLOREST:

Do not share medicines prescribed for you with any other person.

Always use BECLOREST exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

There are two strengths of BECLOREST available, and your doctor will have chosen the strength which best suits your condition.

Do not take more puffs than your doctor has told you to. In some circumstances, your doctor may prescribe more than the usual number of puffs. The usual number of puffs to take is:

Adults

The usual dose is 200 µg twice daily.

In severe cases your doctor may increase the dose to 600 - 800 µg per day.

The maximum daily dose is 1 000 µg (1 mg) per day.

Children

50 – 100 µg should be given two, three or four times daily according to the age and response.

Your doctor may increase the dose to 100 or 200 µg twice daily.

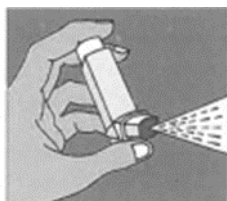
Maximum daily dose: 500 µg daily.

Your doctor will tell you how long your treatment with BECLOREST will last. If you have the impression that the effect of BECLOREST is too strong or too weak, tell your doctor or pharmacist.

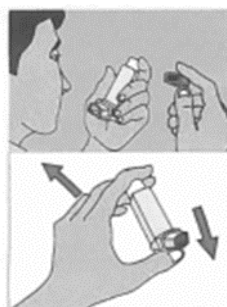
HOW TO USE YOUR INHALER CORRECTLY

Testing your inhaler

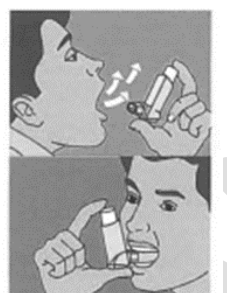
Before using your inhaler for the first time, or if it has not been used for a week or more, 'test fire' it, i.e., release one puff into the air.



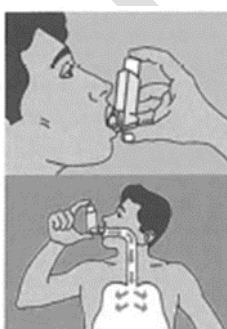
1. Remove the mouthpiece cover and check the mouthpiece thoroughly to see that it is clean. Shake the inhaler vigorously.



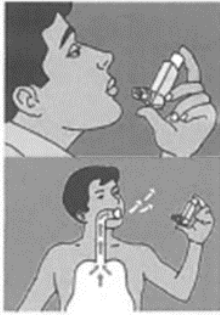
2. Hold the inhaler as shown between index finger and thumb. Breathe out gently through your mouth and immediately place the mouthpiece in your mouth between your teeth (Do not bite it).



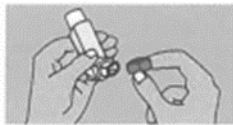
3. Grip the mouthpiece firmly with your lips. Tilt your head slightly backwards. Start breathing in slowly through your mouth. At the same time press the canister as shown, to release one dose while continuing to breathe in steadily and deeply.



4. Remove the inhaler from your mouth. Hold your breath for at least 10 seconds, or if is comfortable. Breathe out slowly.



5. If another dose is required, wait for at least one minute and repeat steps 1 to 4.



After use, replace the mouthpiece cover



NOTE:

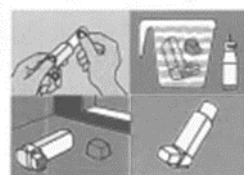
Do not rush stages 2 and 3. It is important to breathe in slowly through your mouth just before pressing the canister. To be sure of using your inhaler properly, you may initially practice these steps in front of a mirror



For children

Young children may need help. To help the child, parents must first learn the technique correctly themselves, then properly guide the child to use the inhaler.

Cleansing



Clean your inhaler at least once a week.

Gently pull the metal canister out of the adaptor of the inhaler. Remove the mouthpiece cover.

Rinse the adaptor and the mouthpiece cover in warm water. But do not put the metal canister into water.

Leave to dry in a warm place. Avoid excessive heat.

Replace the canister and the mouthpiece cover correctly.

If you use more BECLOREST than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BECLOREST

Do not use a double dose to make up for forgotten individual doses.

If you stop taking BECLOREST

This inhaler must be used regularly, even when you feel well. You must not stop using your inhaler unless your doctor tells you to.

4. Possible side effects:

BECLOREST can have side effects.

Not all side effects reported for BECLOREST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BECLOREST, please consult your healthcare provider for advice.

If any of the following happens, stop receiving BECLOREST and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BECLOREST. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- an immediate increase in wheezing, shortness of breath and cough straight after using your inhaler, stop using BECLOREST and use a quick-acting 'reliever' inhaler immediately.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- thrush in the mouth and throat
- hoarseness, throat irritation

Less frequent side effects

- changes to the normal production of the steroids in the body, particularly after treatment with BECLOREST at high doses over a long period of time
- children and adolescents may grow more slowly and may need to have their height checked regularly by their doctor. This occurs particularly after treatment with BECLOREST at high doses over a long period of time

- a decrease in bone mineral density
- eye problems which include the formation of cataracts and glaucoma (increased pressure in the eye)

Side effects with unknown frequency

- movements that serve no purpose
- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
- headache
- nausea

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications. By reporting side effects, you can help provide more information on the safety of BECLOREST.

5. How to store BECLOREST:

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

Protect from direct sunlight or heat.

The canister is pressurised and should not be punctured or burnt even if it seems empty.

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information:

What BECLOREST contains:

The active ingredient is micronized beclomethasone dipropionate.

The other ingredients are HFA-134a (norflurane) and ethanol.

What BECLOREST looks like and contents of the pack:

BECLOREST is a clear solution in a pressurised aluminium canister fitted with a metering valve and an actuator.

BECLOREST 50 is supplied in an aluminium canister fitted with a metering valve, pink plastic actuator, and brown dust cap, packed inside a cardboard carton containing a leaflet.

Each inhaler delivers 200 actuations.

BECLOREST 100 is supplied in an aluminium canister fitted with a metering valve, beige plastic actuator and brown dust cap, packed inside a cardboard carton containing a leaflet.

Each inhaler delivers 200 actuations.

Holder of Certificate of Registration:

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