

BESOMID 100 MCG/ ACTUATION HFA-METERED DOSE INHALER

Beclometasone Dipropionate (100mcg/ actuation)

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What Besomid is used for

Besomid is used to help prevent the symptoms of asthma.

How Besomid works

The active ingredient, beclometasone dipropionate, is one of a group of Medicines called corticosteroids which are often referred to simply as steroids. Besomid reduces the swelling and irritation in the walls of the small air passages in the lungs and so ease breathing problems.

Before you use Besomid

- When you must not use it

If you are pregnant, trying for a baby or breast-feeding. There are a risk of growth retardation and cleft palate to the baby.

If you have ever had lung tuberculosis (TB).

If you have ever had an allergic reaction to Beclomethasone or any ingredients listed at the end of the leaflet.

- Before you start use it

Some medicines are not suitable for people with certain conditions, and sometimes a medicine can only be used if extra care is taken.

Some medicine may increase the effect of Besomid and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

- Taking other medicine

If you are taking or using any other medicines. This includes any medicines you are taking which are available to buy without a prescription, such as herbal and complementary medicines.

How to use Besomid

- How much to use

If this is a new inhaler or if you have not used your inhaler for one week or more, it must be tested before use by removing the mouthpiece cover and pressing down on the canister inside the inhaler. Release one puff into the air, away from you.

For adult, 1 inhalation, three to four times daily or 2 inhalation, twice daily. In more severe cases, 6-8 inhalations daily is recommended, with subsequent reductions. The maximum recommended daily dose of this preparation is 10 inhalations.

For children (6 years and older), 1 inhalation, two to four times daily.

In elderly, refer to your doctor for the dosing.

How to use your inhaler

1. Remove the mouthpiece cover, and check the mouthpiece critically for cleanliness. Shake the inhaler well.
2. Hold the inhaler. Breathe out gently through the mouth and immediately place the mouthpiece in the mouth.
3. Close the lips around the mouth piece firmly. Tilt the head slightly backwards. Start breathing in slowly through the 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 the mouth. Hold the breath at least for 10 seconds, or as long as is comfortable. Breathe out slowly.
5. If another dose is required, wait for at least one minute before repeating steps 1 to 4. After use, place mouthpiece cover.

Cleansing

Clean the inhaler at least one a week.

1. Gently pull the metal canister out the plastic body of the inhaler. Remove the mouthpiece cover.
2. Rinse the plastic body and the mouthpiece cover in warm water.
3. Leave to dry in warm place. Avoid excessive heat.
4. Replace the canister and the mouthpiece cover correctly.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Besomid for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Acute overdosage can cause suppression of immune and inflammatory reactions.

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While you are using it

- Things you must do

Your doctor may prescribe this inhaler to replace steroid tablets, which may mean for a short time you have to take both medicines. It is important to follow your doctor's advice. Whilst you are reducing the number of steroid tablets that you take you may feel generally unwell even though you can breathe as well as normal or better.

- Things you must not do

Do not stop taking steroid suddenly. If you have other allergies, you may find that stopping your steroid tablets makes them worse. If this happens, keep using your inhaler and tell your doctor. There may be times when you need to take steroid tablets as well as using your inhaler, for example if you have worsening asthma attacks, you get a chest infection or you need an operation. Your doctor may give you a small supply of steroid tablets to be taken in these situations; if he does, you will be given full instructions on how and when to take them. Contact your doctor immediately if you think that you need to take steroid tablets, even if you have your own supply.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the medicine make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Visit your doctor regularly for a review of your condition. If you have to go into hospital, remember to take all your inhalers and other medicines with you.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If immediately after taking a puff of this inhaler, you feel wheezy or tight chested do not take any more puffs. Use your reliever

inhaler to help your breathing and contact your doctor immediately. Stop using your inhaler and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

Nausea, cough and give unpleasant taste and smell.

An allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

Other than that are fungal infection of the throat and mouth, hoarseness may develop in some people. Systemic effects of inhaled corticosteroids may occur particularly at high doses prescribed for prolonged periods. These may include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cloudy eye lens and increase eye pressure.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.moh.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Besomid

- Storage

Store below 30°C. Do not freeze. Avoid storage in direct sunlight or heat. Do not use this medicine after the expiry date that is stated on the outer packaging after EXP. The expiry date refers to the last day of that month.

- Disposal

The canister is pressurised and should not be punctured or burnt even if it seems empty. Do not throw any medicines via wastewater or household waste. If your doctor decides to stop treatment, return the inhaler to your doctor or pharmacist for safe

disposal. These measures will help to protect the environment.

Product Description

- What it looks like

An aerosol containing a clear solution, filled in a suitable pressurized aluminum container fitted with metering valve provided with oral inhaler actuator.

- Ingredients

- Active ingredient
Beclometasone Dipropionate

- Inactive ingredients
Ethanol
Oleic Acid
Propellant HFA 134a

- MAL number

MAL08080386ACZ

Manufacturer

Midas Care Pharmaceuticals Pvt. Ltd.
B-16 MIDC, Waluj, Chhatrapati
Sambhajnagar 431-136 India

Product Registration Holder

Steriline Sdn. Bhd.
Lot 5979, Jalan Teratai
5 1/2 Mile Off Jalan Meru
41050 Klang, Selangor

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