

BIOSONE® 100 mcg/dose HFA Inhalation Aerosol

Beclometasone dipropionate 100 mcg/dose

What is in this leaflet

1. What Biosone® is used for
2. How Biosone® works
3. Before you use Biosone®
4. How to use Biosone®
5. While you are using Biosone®
6. Side effects
7. Storage and disposal of Biosone®
8. Product description
9. Manufacturer and Product registration holder
10. Date of RiMUP revision

What Biosone® is used for

The active component of Biosone® is Beclometasone Dipropionate, which is an anti-inflammatory corticosteroid. It helps to prevent asthma in people who need regular treatment. This is why it is sometimes called ‘preventer’.

How Biosone® works

Biosone® works by reducing swelling and irritation in the lungs. It is a pressurized, metered-dose aerosol intended for oral inhalation only. It is an environment friendly inhaler.

Before you use Biosone®

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

-When you must not use it

Do not take Biosone® if you are allergic (hypersensitive) to:

- Beclometasone Dipropionate
- Lactose or milk protein
- Any of the other ingredients of Biosone®
- Do not use Biosone® if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before using Biosone®

Pregnancy and lactation

Do not take Biosone® if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Biosone® if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it:

Check with your doctor, nurse or pharmacist before taking your medicine if:

- You have ever been treated for tuberculosis (TB)
- You are using beclometasone at the same time as taking steroid tablets or if you have just finished taking steroid tablets.

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

- Taking other medicines:

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Biosone®

-How much to use:

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

-When to use it:

Use as directed by your doctor or pharmacist.

-How long to use it:

Continue taking Biosone® 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. However, if it is almost time for your next dose, wait until the usual time to take your 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):

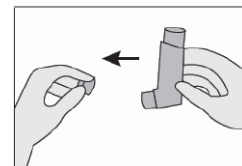
Contact your doctor immediately or go to the Emergency department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Biosone®

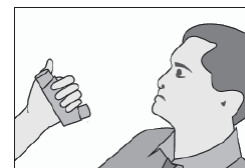
-Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Biosone® .
- Tell your doctor immediately if you become pregnant while taking this medication.

Instruction for use:



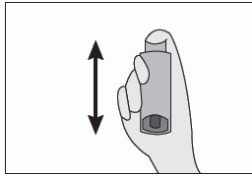
If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of ten days, “test spray” the inhaler. Remove the cap from the mouthpiece;



The mouthpiece should be inspected for the presence of foreign objects before each use.

BIOSONE[®] 100 mcg/dose HFA Inhalation Aerosol

Beclometasone dipropionate 100 mcg/dose



Spray the inhaler 2 times into the air after shaking the device prior to each actuation. Make sure the canister is fully and firmly inserted into the actuator.

Hold the inhaler upright with your thumb on the base. Place either one or two fingers on the top of the canister.

A handy tip for children

Children and others who have weaker hands may have difficulty pressing down on the top of the can with just one hand. They can use both hands to make their inhaler work.

Breathe out fully through your mouth expelling as much air from your lungs as possible.



Thereafter, place the mouthpiece of the inhaler in your mouth between your teeth.

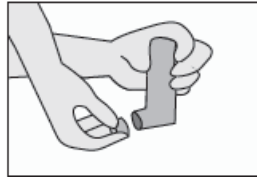


Close your lips around it (do not bite it), tilt your head slightly backwards. Start breathing in slowly through your mouth.



As you breath in steadily and deeply, press down the canister to release one puff.

While holding your breath, you should not take off the inhaler from your mouth and should continue holding your breath for 10 seconds or for as long as it is comfortable. Breath out slowly.



After use, replace the mouthpiece cover.

Cleaning:

Keeping the plastic actuator clean is very important to prevent medicine buildup and blockage. The actuator should be washed, shaken to remove excess water and air-dried thoroughly at least once a week. The inhaler may stop spraying if not properly cleaned.

1. Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.
2. Rinse the plastic body and the mouthpiece cover in warm/ running water.
3. Dry thoroughly. Avoid excess heat.
4. Repeat the canister and the mouthpiece cover correctly.
5. Do not put the metal canister in water.

-Things you must not do

- Do not stop using Biosone[®] unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Biosone to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

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

drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Biosone[®] 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 like skin rashes, redness, itching etc.
- Your breathing or wheezing gets worse straight after using your inhaler.

Visit your doctor or pharmacist immediately if you experience any of the side effects after taking this medicine.

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

Storage and disposal of Biosone[®]

Storage:

Keep medicine out of reach of children.

Store below 30°C. Protect from direct sunlight and heat.

Disposal:

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose medicine no longer required. These measures will help to protect the environment.

Product description

-What it looks like:

Biosone[®] is a bulk preparation for inhalation, supplied in a pressurized container. On visual examination, the pressurized container has no sign of

BIOSONE[®] 100 mcg/dose HFA Inhalation Aerosol

Beclometasone dipropionate 100 mcg/dose

physical damage or leakage. The product is a clear solution.

-Ingredients:

Active Ingredients:

-Beclometasone dipropionate BP

Inactive Ingredients:

-Dehydrated alcohol

-Tetra-fluoro ethane (HFA 134a)

-MAL No.:

MAL16115015AZ

Manufacturer

BioCare Manufacturing Sdn. Bhd.

Lot 269, Taman Farmaseutikal,
Bandar Baru Seri Iskandar, 32610 Seri
Iskandar, Perak, Malaysia.

Product Registration Holder

BioCare Manufacturing Sdn. Bhd.

No 67, Jalan Gasing,
46000 Petaling Jaya, Selangor.

Date of revision

29/09/2025

Serial Number:

NPRA(R2/1)220224/839