

BIOSONIDE 200 mcg HFA METERED DOSE INHALER

Budesonide (200 mcg/actuation)

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What BIOSONIDE is used for

BIOSONIDE is used for the regular treatment of asthma.

How BIOSONIDE works

BIOSONIDE contains active ingredient budesonide that belongs to a group of medicine called corticosteroids. It works by reducing and preventing swelling and inflammation in the airways caused by asthma. BIOSONIDE is intended for regular use and not for rapid relief of acute asthma conditions. It may take some weeks before you receive full effect of the treatment.

Before you use BIOSONIDE

-When you must not use it

Do not take BIOSONIDE if:

- you are allergic (hypersensitive) to the active ingredient (budesonide) or any ingredients used in this product.

-Before you start to use it:

Check with your doctor, nurse or pharmacist before taking your medicine if you have any of the following conditions:

- Pulmonary tuberculosis (bacterial infections of the lungs)
- Chicken pox
- Measles

Replacement of systemic steroid therapy (treatment that reaches cells

throughout the body by travelling through the bloodstream) with inhaled therapy may unmask allergies such as allergic rhinitis (inflammation of the inside of the nose) or eczema previously controlled by systemic therapy.

You should rinse your mouth out with water after each dosage to minimize the risk of fungal infection in your mouth and throat. You must contact your doctor if your asthma gets worse. This may mean that the dosage needs to be changed or that you need other treatment.

In an acute asthma attack you must use your fast-acting asthma medicine.

- 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. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines used for treating fungal infections (such as ketoconazole or itraconazole).

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

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

How to use BIOSONIDE

-How much to use:

- Always use BIOSONIDE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will prescribe the correct dose for you. The number of doses

varies according to the severity of your asthma.

Children aged 2-7 years:

200-400 mcg per day in two divided doses.

Children aged 7 years and older:

200-800 mcg per day in two divided doses

Adults:

200-1600 mcg per day in two divided doses.

For maintenance treatment administration, twice daily, morning and evening is sufficient. The maintenance dose should be the lowest possible. Following a single dose, an effect may be expected after a few hours. The full therapeutic effect is only achieved after a few weeks of treatment.

-When to use it:

You must use BIOSONIDE regularly, i.e. each day, even if you have no symptoms. BIOSONIDE is entirely driven by your own inhalation. The medicine follows the inhaled air down to the airways. Therefore, it is important to breathe in deeply and forcefully when you take your dose.

Note that the amount of medicine is very small and it can be very hard to notice. You might not be able to taste or detect the medicine in any way. However, if you follow the instructions for use, you can be sure that you inhaled the dose.

-How long to use it:

Continue taking BIOSONIDE 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

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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.

Overdosage of budesonide may cause adrenal suppression (adrenal glands located on top of each kidney, unable to produce a sufficient amount of cortisol hormone).

While you are using BIOSONIDE

-Things you must do

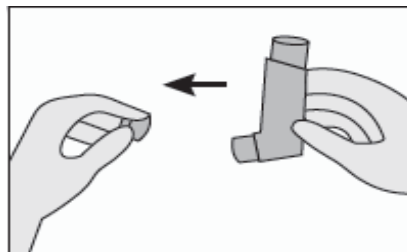
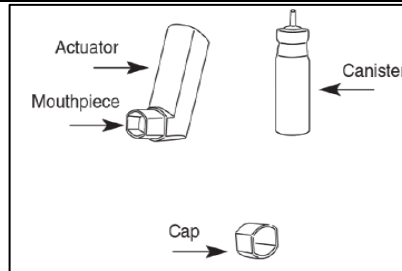
- Use BIOSONIDE exactly as directed by your doctor.
- Rinse your mouth with water after each dosing to minimize the risk of fungal infection.
- Tell your doctor immediately if you become pregnant while taking this medication.

Instruction for use:

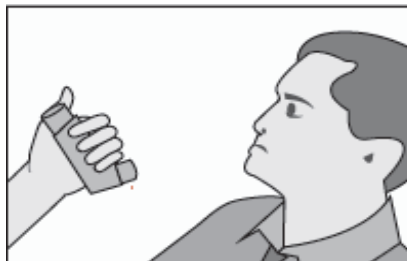
Shake the inhaler 3 – 5 times in an up-down motion before each puff to mix the contents of the canister.

If the device is being used for the first time, prime it by actuating the canister mid-air until an even spray is obtained. For inhalers that are not used for more than 2 weeks, it should be primed before use.

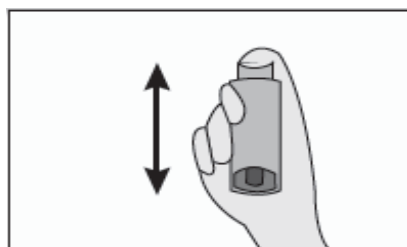
Using your inhaler:



- 1) Remove the cap from the mouthpiece of the actuator.



- 2) Make sure the mouthpiece is clean inside and outside.



- 3) Hold the inhaler by placing your index finger on top of the metal canister and thumb on the bottom of the plastic mouthpiece. Shake it well.



- 4) Raise the inhaler to your mouth. Put the mouthpiece between your teeth, but do not bite it. Close your lips around the mouthpiece. Breathe out slowly and gently through the inhaler until your lungs feel comfortably empty.



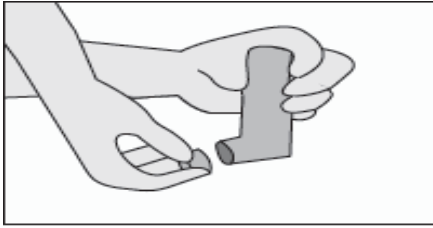
- 5) Tilt your head back slightly. Start to breathe in slowly through your mouth. As you start to breathe in, press down firmly on the top of the can to release your medicine. Continue to breathe in steadily and deeply.



- 6) Hold your breath. Remove the inhaler from your mouth. Continue to hold your breath as long as possible, up to 10 seconds. Then breathe out gently. If you are taking a second puff, wait about one minute, then repeat steps 3 to 6.

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- 7) Replace the mouthpiece after each use.

Cleaning:

Keeping the plastic actuator clean is very important to prevent medicine build up 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.

How to clean your inhaler:

1. Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
2. Rinse the actuator thoroughly with warm water.
3. Dry the actuator thoroughly inside and outside.
4. Replace the metal canister and mouthpiece cover.
5. Do not put the metal canister in water.

-Things you must not do

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

-Things to be careful of

Pregnancy and breastfeeding

- If you are pregnant or planning to get pregnant, talk to your doctor before using BIOSONIDE.
- BIOSONIDE should be used during pregnancy only if clearly needed as studies in human cannot rule out the possibility of harm.

Driving and using machines

BIOSONIDE has no or negligible effect on your ability to drive or to use tools or machines.

Side effects

Like all medicines, BIOSONIDE 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.

Common

- Mild irritation in the throat
- Candida infection in the oropharynx
- Hoarseness of voice
- Coughing

Rare

- Nervousness, restlessness
- Behavioral disturbances, depression
- Skin bruising
- Immediate and delayed hypersensitivity reactions including rash/ contact dermatitis/ urticaria/ angioedema and bronchospasm

Possible systemic effects of inhaled steroids may occur particularly at high doses for prolonged periods. These effects include adrenal suppression (adrenal glands do not produce adequate amounts of steroid hormones), growth retardation in children and adolescents, decrease in bone density and cataract and glaucoma (build-up of pressure within the eye) in the eyes.

It is recommended that the height of children receiving prolonged therapy be regularly monitored.

Pneumonia (infection of the lung) in COPD patients (common side effect)

- Tell your doctor if you have any of the following while taking BIOSONIDE they could be symptoms of a lung infection:

- Fever or chills
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties.

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.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

Storage and disposal of BIOSONIDE

Storage:

Keep medicine out of reach and sight of children.

Store below 30°C. Do not freeze. Protect from direct sunlight.

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:

Biosonide 200 mcg HFA Metered Dose Inhaler is a white to almost white suspension packed in an aluminium canister (20ml) fitted with a plastic (EPDM) metering valve (50 mcl) and a polypropylene plastic maroon actuator with a polypropylene plastic grey dust cap. The aluminium canister is labeled and then packed into an outer carton, along with a package insert. On visual examination there must be no sign of physical damage or leakage.

-Ingredients:

Active Ingredients:

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Budesonide (200 mcg/actuation)

-Budesonide

Inactive Ingredients:

-1,1,1,2-Tetrafluoroethane (HFA 134a)

-MAL No.:

MAL

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, Malaysia.

Date of revision

26 March 2024

Serial Number:

NPRA (R2) 24/052