

BUDESONIDE PRESSURISED INHALATION

Budesonide (200mcg/actuation)

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What Budesonide Pressurised Inhalation is used for

Budesonide Pressurised Inhalation is used for the regular treatment of asthma.

How Budesonide Pressurised Inhalation works

Budesonide Pressurised Inhalation belongs to a group of medicines called corticosteroids. It relieves and prevents inflammation in the airways caused by asthma. Budesonide Pressurised Inhalation is intended for regular use and not for rapid relief of acute asthma conditions. It may take some weeks before you receive the full effect of the treatment.

Before you use Budesonide Pressurised Inhalation

When you must not use it

In case of hypersensitivity to the active substance or to the excipient.

Before you start to use it

Tell your doctor or pharmacist if you have any of the following conditions:

- i) pulmonary tuberculosis (bacterial infections of the lungs),
- ii) chicken pox,
- iii) 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 minimise 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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may affect or be affected by treatment with Budesonide Pressurised Inhalation, for example medicines containing ketoconazole or itraconazole (present in medicines for fungal infections).

How to use Budesonide Pressurised Inhalation

How much to use

Always use Budesonide Pressurised Inhalation exactly as your doctor

has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor prescribes the correct dose for you. The number of doses varies according to the severity of your asthma.

Children aged 2-7 years:

200-400 micrograms per day in two divided doses.

Children aged 7 years and older:

200-800 micrograms per day in two divided doses.

Adults:

200-1600 micrograms 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 Budesonide Pressurised Inhalation regularly, i.e. each day, even if you have no symptoms. Budesonide Pressurised Inhalation 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, see "Instructions for use".

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 have inhaled the dose.

How long to use it

Continue taking Budesonide Pressurised Inhalation for as long as your doctor recommends.

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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.

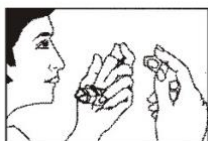
Overdosage of budesonide may cause adrenal suppression (adrenal glands located on top of each kidney, unable to produce a sufficient amount of cortisol hormone).

While you are using Budesonide Pressurised Inhalation

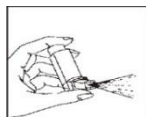
Things you must do

Use Budesonide Pressurised Inhalation as directed by your doctor. Rinse your mouth with water after each dosing to minimize the risk of fungal infection.

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 seven 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.

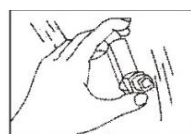


Spray the inhaler 2 times into the air after shaking the device prior to each actuation. (See pic no. 1)



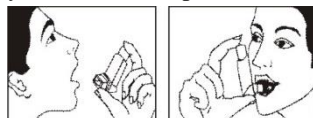
1

Make sure the canister is fully and firmly inserted into the actuator. (See pic no. 2)



2

Hold the inhaler upright with your thumb on the base. Place either one or two fingers on the top of the canister. 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. (See pic no. 3)



3

Close your lips around it (do not bite it) tilt your head slightly backwards. Start breathing in slowly through your mouth. As you breathe in steadily and deeply, press down the canister to release one puff. (See pic no. 4)



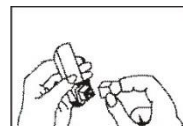
4

While holding your breath, you should take off the inhaler from your mouth and should continue holding your breath for 10 seconds or for as long as it is comfortable. Breathe out slowly. (See pic no. 5)



5

If the second dose is required, wait for at least one minute and repeat steps 2 through 5 for each puff prescribed by your physician. Rinse your mouth or gargle with water after inhaling your recommended dose. After use, replace the mouthpiece cover. (See pic no.6)



6

Practice in front of the mirror for the first few times. If you see 'mist' coming from top of the inhaler or sides of the mouth, this indicates failure of technique. Start again from Step 2. (See pic no. 7)

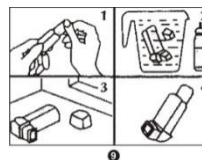


7

Cleaning:

Clean the inhaler at least once in a week.

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. Replace the canister and the mouthpiece cover correctly.



8

Discard the inhaler along with the canister after using the labelled number of inhalation.

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Things you must not do

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

Things to be careful of

Pregnancy and breastfeeding

Budesonide should be used during pregnancy only if clearly needed as studies in human cannot rule out the possibility of harm.

Side effects

Like all medicines, Budesonide Pressurised Inhalation can cause side effects, although not everybody gets them.

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 (buildup of pressure within the eye) in the eyes.

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

Common: Mild irritation of the throat, coughing, hoarseness, fungal infection in the mouth cavity and throat.

Rare: Hives and other skin rashes, angioedema (swelling of the face, lips, tongue and/or throat, occasionally combined with difficulty breathing or swallowing), bronchospasm (contraction of the

airway muscles), bruising.

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:03-78835550, or visiting the website portal.bpfk.gov.my (Consumers Reporting).

Storage and disposal of Budesonide Pressurised Inhalation

Storage

Keep out of the reach and sight of children.

Do not store above 25°C and do not freeze. Keep the protective cap on the inhaler.

Do not use Budesonide Pressurised Inhalation after the expiry date which is stated on the inhaler and the packaging (EXP). The expiry date refers to the last day of that month

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

White to off white suspension filled in aluminium aerosol can with silver colour ferrule valve provided with actuator suitable for oral inhalation, when actuated a metered spray is produced.

Ingredients

Active ingredients

Each metered dose contains: Budesonide BP 200mcg suspended in inert aerosol propellant.

Inactive ingredients

Propellant HFA 134a/p, Sorbitan Trioleate BP, Ethanol.

MAL Number:

MAL 07081527AZ

Manufacturer

Glenmark Pharmaceuticals Ltd

(Unit III) Village Kishanpura, Baddi – Nalagarh Road, Tehsil Nalagarh, Distt. Solan (H.P.) – 174101, India

Product Registration Holder

Biocare Pharmaceutical (M) Sdn Bhd

No 28G, 28-1 & 28-2, Pusat Dagangan PJCC, Jalan PJS 5/28, 46150 Petaling Jaya, Selangor.

Date of revision

30 June 2015

Serial number

BPFK(R4/1)190615/00157