Biosone™ 100mcg/dose HFA Inhalation Aerosol

Beclometasone dipropionate BP

Description: Biosone 100mcg/dose HFA Inhalation Aerosol is a white to almost white clear solution, supplied in a pressurized container, packed in an aluminium canister (19ml) fitted with a plastic metering valve (50mcl) and a plastic actuator with dust cap (brown). The aluminium canister is labelled and then packed into an outer carton, along with a package insert. On visual examination, there should be no sign of physical damage or leakage.

Pharmacodynamics: The active ingredient of Biosone 100 HFA Inhaler is Beclometasone Dipropionate (BDP) (ATC-Code R03 BA01) a topical corticosteroid endowed with potent anti-inflammatory and anti-allergic activity on the airways mucosa. Beclometasone dipropionate, administered by inhalation and in recommended doses, has a glucocorticoid anti-inflammatory action within the lungs but no systemic effect.

Indication: Indicated for the prophylactic management of mild, moderate or severe asthma.

Pharmacokinetics: Absorption when administered via inhalation by a MDI: Systemic absorption of unchanged beclometasone dipropionate (BDP) occurs through the lungs. There is negligible oral absorption of the swallowed dose of unchanged BDP. Prior to absorption there is extensive conversion of BDP to its active metabolite B-17-MP. The systemic absorption of B-17-MP arises from both lung deposition (36%) and oral absorption of the swallowed dose (26%).The absolute bioavailability following inhalation is approximately 2% and 62% of the nominal dose for unchanged BDP and B-17-MP, respectively. BDP is absorbed rapidly with peak plasma concentrations observed (tmax) at 0.3 hour. B-17-MP appears more slowly with a tmax of 1 hour. There is an approximately linear increase in systemic exposure with increasing inhaled dose. When administered orally the bioavailability of BDP is negligible but presystemic conversion to B-17-MP results in 41% of the dose being absorbed as B-17-MP.
Distribution: The tissue distribution at steady-state for BDP is moderate (20 L) but more extensive for B-17-MP (424 L). Plasma protein binding is moderately high (87%). Biotransformation: BDP is cleared very rapidly from the systemic circulation, by metabolism mediated via esterase enzymes that are found in most tissues. The main product of metabolism is the active metabolite (B-17-MP). Minor inactive metabolites, beclometasone-21-monopropionate (B-21-MP) and beclometasone (BOH), are also formed but these contribute little to the systemic exposure.
Elimination: The elimination of BDP and B-17-MP are characterized by high plasma clearance (150 L/hour and 120 L/hour) with corresponding terminal elimination half-lives of 0.5 hour and 2.7 hour. Following oral administration of titrated BDP, approximately 60% of the dose was excreted in the faeces within 96 hours mainly as free and conjugated polar metabolites. Approximately 12% of the dose was excreted as free and conjugated polar metabolites in the urine. The renal clearance of BDP and its metabolites is negligible.

Dosage/ Use Instruction:
The recommended total daily dose of Biosone is lower than that for current CFC-BDP products and should be adjusted to the individual patient.

Proper instruction and good inhaler technique is necessary to get maximum benefit from Biosone. For patients who are unable to successfully coordinate actuation of the metered dose inhaler with inhalation Biosone should be substituted. Patients should be advised that Biosone may have a different taste and feel than a CFC inhaler.

Biosone delivers a consistent dose of beclomethasone dipropionate.

Whether or not the canister is shaken
Without the need for the patient to wait between individual actuations
Regardless of storage orientation
Regardless of periods without use of up to 14 days (do not need to test fire)
At temperatures as low as -10°C

Patients should be instructed to rinse their mouth out each time after using Biosone.

Use of a spacer with Biosone inhalers reduces the amount of drug deposited in the oropharynx without affecting drug deposition in the lungs.

Starting and Maintenance Dose:
The recommended dose of Biosone in adults is as follows:-
For mild to moderate asthma: 50µg to 200µg twice daily
For more severe asthma: doses up to 400µg twice daily
Maximum recommended daily dose: 800µg

In children aged five years and over the recommended dose of Biosone is 50µg twice daily.

Biosone must be used on a regular basis even when patients are asymptomatic. When patients' symptoms remain satisfactorily controlled the dose of Biosone can be gradually reduced to the minimum effective dose to maintain control. Doses of BDP can be titrated up or down by switching between 50mcg dose and 100mcg as required.

Comparative clinical studies show that asthma patients achieve equivalent pulmonary function and control of symptoms with Biosoneat lower total daily doses than CFC-BDP inhalers. These studies demonstrated clinical equivalence between CFC-BDP and Biosonewhen given in a dose ratio of 2.5 to 1.

Transferring Patients from a CFC-BDP Inhaler to Biosone:

Step 1 - Consider the dose of CFC-BDP appropriate to the patients' current condition. Symptomatic patients may require an increased dose of CFC-BDP and this increased dose should be considered in transferring patients to Biosone.

Step 2 - Convert the appropriate CFC-BDP dose to the Biosone dose according to the table below:

Daily Dose of Beclomethasone Dipropionate (µg)							
CFC-BDP	200-250	300	400-500	600-750	800-1000	1200-1500	1600-2000
Biosone	100	150	200	300	400	600	800

SPECIAL PATIENT GROUPS
Elderly and Patients with Hepatic or Renal Impairment
No special dosage recommendations are made.

Patients Not Receiving Systemic Corticosteroids
For patients who are inadequately controlled with bronchodilators and who are not receiving systemic corticosteroids, it is recommended that they continue to use a bronchodilator when treatment with Biosone commences. Any improvement in respiratory function is usually apparent in 1 to 4 weeks. Some of the patients who do not respond during this period may have excessive mucus in their bronchi so that the drug is unable to penetrate to its site of action. A short course of systemic steroids in relatively high dosage should be given to eliminate mucus and other inflammatory changes in the lungs. Continuation of treatment with Biosone usually maintains the improvement achieved with the oral steroid while it is being withdrawn gradually. Exacerbation of asthma caused by infection is usually controlled by appropriate antibiotic treatment and, if necessary, by increasing the dose of Biosone. However, it may be necessary to give a short, intensive course of systemic steroids to tide over the duration of the stress.

Steroid Dependent Patients
As recovery from impaired adrenocortical function, caused by prolonged systemic steroid therapy is slow, adrenocortical function should be monitored regularly. The patient's asthma should be in a stable state before being given inhaled steroids in addition to the usual maintenance dose of systemic steroid.

Withdrawal of systemic steroids should be gradual, starting about seven days after the introduction of Biosone therapy. For daily oral doses of prednisolone of 10mg or less, dose reduction in 1mg steps at intervals of not less than one week is recommended. The dose reduction scheme should be chosen to correlate with the magnitude of the maintenance systemic steroid dose.

Some patients feel unwell experiencing aches and pains, tiredness and even depression during withdrawal phase despite maintenance or even improvement of respiratory function. These withdrawal symptoms should be treated symptomatically and the patient should be encouraged to preserve with the inhaler and withdrawal of systemic steroids. However, if there are objective signs of adrenal insufficiency, it may be necessary to resume systemic steroid treatment temporarily.

Most patients can be successfully transferred to inhaled steroids with maintenance of good respiratory function, but special care is necessary for the first months after the transfer until the hypothalamic-pituitary-adrenal (HPA) system has sufficiently recovered to enable the patient to cope with emergencies such as trauma, surgery or severe infections. It may be advisable to provide such patients with a supply of oral steroid to use in such emergencies. The dose of inhaled steroids should be increased at this time and then gradually reduced to the maintenance level after the systemic steroid has been discontinued.

Discontinuation of systemic steroids may cause exacerbation of allergic diseases such as atopic eczema and rhinitis previously controlled by the systemic drug. These should be treated symptomatically with antihistamines and/or topical therapy.

Contraindication: Hypersensitivity to Beclometasone inhaler is a contraindication; and special care is necessary in patients with active or quiescent pulmonary tuberculosis.

Warnings: Patients should be properly instructed on the use of the inhaler to ensure that the drug reaches the target areas within the lungs. Patients should also be informed that Biosone 100 mcg/dose HFA Inhalation Aerosol should be used on a regular basis, even when they are asymptomatic. Biosone 100 mcg/dose HFA Inhalation Aerosol does not provide relief of acute asthma symptoms, which require a short-acting inhaled bronchodilator. Patients should have relief medication available.

Severe asthma requires regular medical assessment, including lung-function testing, as there is a risk of severe attacks and even death. Patients should be instructed to seek medical attention if short-acting relief bronchodilator treatment becomes less effective, or more inhalations than usual are required as this may indicate deterioration of asthma control. If this occurs, patients should be assessed and the need for increased anti-inflammatory therapy considered (eg. Higher doses of inhaled corticosteroid or a course of oral corticosteroid).

Severe exacerbations of asthma must be treated in the usual way, ie. By increasing the dose of inhaled beclometasone dipropionate, giving a systemic steroid if necessary, and/or an appropriate antibiotic if there is an infection, together with β-agonist therapy. Treatment with Biosone 100 mcg/dose HFA Inhalation Aerosol should not be stopped abruptly. Systemic effects of inhaled corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. These effects are much less likely to occur than with oral corticosteroids.

Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma. It is important that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained. It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of inhaled corticosteroids, if possible, to the lowest dose at which effective control of asthma is maintained.

In addition, consideration should also be given to referring the patient to a paediatric respiratory specialist. Prolonged treatment with high doses of inhaled corticosteroids may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. The transfer to Biosone 100 mcg/dose HFA Inhalation Aerosol of patients, who have been treated with systemic steroids for long periods of time or at high doses, needs special care, since recovery from possible adrenocortical suppression may take considerable time.

Reduction of the dose of systemic steroid can be commenced approximately one week after initiating treatment with **Biosone 100 mcg/dose HFA Inhalation Aerosol.** The size of the reduction should correspond to the maintenance dose of systemic steroid. For patients receiving maintenance doses of 10mg daily or less of prednisolone (or equivalent) reductions in dose of not more than 1 mg are suitable. For higher maintenance doses, larger reductions in dose may be appropriate. These oral dosage reductions should be introduced at not less than weekly intervals. Adrenocortical function should be monitored regularly as the dose of systemic steroid is gradually reduced.

Some patients feel unwell during withdrawal of systemic steroids despite maintenance or even improvement of respiratory function. They should be encouraged to persevere with inhaled beclometasone dipropionate and to continue withdrawal of systemic steroid, unless there are objective signs of adrenal insufficiency. Patients weaned off oral steroids whose adrenocortical function is impaired should carry a steroid warning card indicating that they may need supplementary systemic steroids during periods of stress, eg. Worsening asthma attacks, chest infections, major intercurrent illness, surgery, trauma, etc.

Replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by the systemic drug. These allergies should be symptomatically treated with antihistamine and / or topical preparations, including topical steroids. As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis. Patients should be advised that this product contains small amounts of ethanol (approximately 4.320 mg per actuation) and glycerol. At the normal doses, the amounts of ethanol and glycerol are negligible and do not pose a risk to patients.

Side effects: Candidiasis of the mouth and throat (thrush) occurs in some patients, the incidence of which is increased with doses greater than 400mcg Beclometasone dipropionate per day. Patients with high blood levels of Candida precipitins, indicating a previous infection, are most likely to develop this complication. Some patients may find it helpful to rinse their mouth thoroughly with water after using the inhaler. Symptomatic candidiasis can be treated with topical antifungal therapy whilst still continuing with the Beclometasone inhaler. In some patients, inhaled Beclometasone dipropionate may cause hoarseness or throat irritation. It may be helpful to rinse mouth with water immediately after inhalation. As with other inhalation therapy, the potential for paradoxical bronchospasm should be kept in mind. If it occurs, the preparation should be discontinued immediately and alternative therapy instituted.

Interactions with other medicaments: Beclomethasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

There are no known interactions of inhaled corticosteroids with other drugs. The use of inhaled sympathomimetic drug prior to inhalation of steroid may improve the lung distribution. If used concomitantly with systemic or intranasal steroids the suppressive effect on adrenal function may be potentiated.

Pregnancy and lactation: The safety of Beclometasone dipropionate for use in human pregnancy has not been established. Reproduction toxicity studies in animals have revealed an increased incidence of foetal damage, the significance of which is considered uncertain in man. Since the possibility of suppression of the adrenal cortex in the newborn baby after long-term treatment must be considered the needs of the mother must be carefully weighed against the risk of the foetus. It is reasonable to assume that the drug is distributed into the breast milk, but at the dosages used for direct inhalation, there is low potential for significant levels in breast milk.

Symptoms and Treatment of Overdose: Acute: Inhalation of doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not require emergency action. In these patients treatment should be continued at a dose sufficient to control asthma; adrenal function recovers in a few days and can be verified by measuring plasma cortisol.
Chronic: Use of inhaled beclomethasone dipropionate in daily doses in excess of 1,500mcg over prolonged periods may lead to adrenal suppression. Monitoring of adrenal reserve may be indicated. Treatment should be continued at a dose sufficient to control asthma.

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

Shelf life: 3 years

Dosage form and packaging available: Pressurised Metered-Dose Inhaler canister contains 200 metered doses, each containing 100mcg of Beclometasone dipropionate BP. It does not contain CFC as propellant.

Distributed by:
Biocare Pharmaceutical (M) Sdn. Bhd. (652530-K)

BioCare

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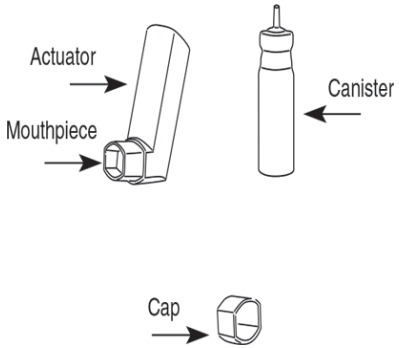
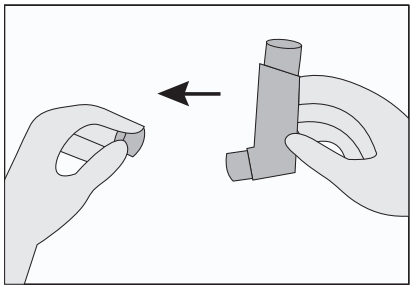
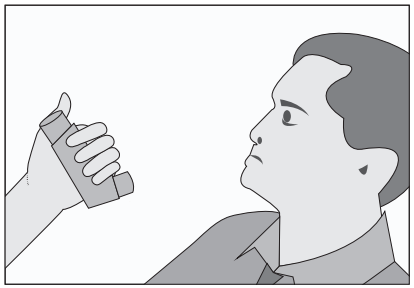
HOW TO USE YOUR INHALER CORRECTLY

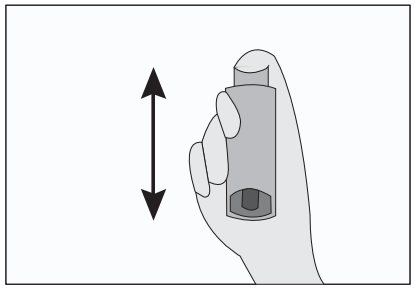




1. If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of ten days, "test spray" the inhaler. Remove the cap from the mouthpiece; the mouthpiece should be inspected for the presence of foreign objects before each use.



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



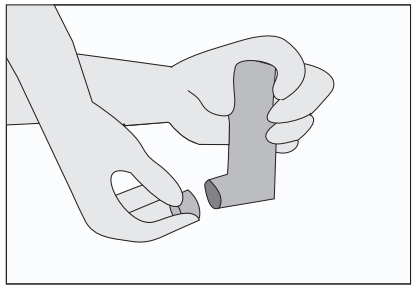
3. Spray the inhaler 2 times into the air after shaking the device prior to each actuation. Make sure the canister is fully and firmly inserted into the actuator. Hold the inhaler upright with your thumb on the base. Place either one or two fingers on the top of the canister. Breathe out fully through your mouth expelling as much air from your lungs as possible.

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

5. 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.

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

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.

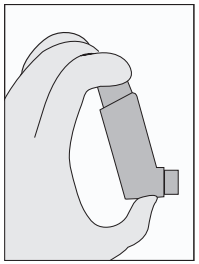


7. Replace the mouthpiece cap after each use.

In case of emergency situation when you feel you are not relieved despite using your inhaler, you can use inhaler along with spacer (a device that your doctor advise to use with your inhaler). This may save your life on the way to hospital. For more information, consult with your doctor.

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.



Cleaning your Inhaler

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.

Shake well the inhaler before each use

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 /running water.
3. Dry the actuator thoroughly inside and outside.
4. Replace the metal canister and the mouthpiece cover.
5. Do not put the metal canister in water.

Your Inhaler should be cleaned at least once a week

Precaution

1. Pressurised canister, do not puncture, break or incinerate even when apparently empty.
2. Avoid storage in direct sunlight or heat.
3. Store below 30° C
4. Keep away from eyes
5. Keep away from children
6. Handle the inhaler with care when using with other device i.e spacer or nebulizer to avoid damaged to the inhaler.