# **BIOSONIDE** 200 mcg HFA Metered Dose Inhaler

**Composition**
Each actuation delivers Budesonide 200 mcg.

**Description**
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.

**Pharmacodynamics**
Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralcorticoid activity. The precise mechanism of corticosteroid action on inflammation in asthma is not known. Corticosteroids have been shown to have a wide range of inhibitory activities against multiple cell types (mast cells, eosinophils, macrophages and lymphocytes) and mediators (e.g. histamine, eicosanoids, leukotrienes and cytokines) involved in allergic and non-allergic mediated inflammation.

**Pharmacokinetics**
**Pharmacology**
Budesonide is a potent glucocorticoid that when given systemically has standard glucocorticoid activity and binds with high affinity to the glucocorticoid receptor. The drug was developed primarily for topical use. Budesonide, if given systematically, has catabolic and antianabolic effect on proteins in peripheral tissues; it causes resistance to insulin and impair the peripheral utilization of glucose as well as causing increased calcium loss from bone via the kidney. However budesonide depends for its effects on the local anti-inflammatory and immunosuppressive activity. It has been shown in animal studies to have a high ratio of topical to systemic activity compared with other corticosteroids including beclomethasone dipropionate, flunisolide, flucinolone acetonide, and triamcinolone acetonide. Results of a study of hamsters with induced ileitis suggested that the anti-inflammatory effect of budesonide was due to local rather than systemic effects. Inhaled glucocorticosteroid reduce the number of inflammatory cells such as eosinophils, lymphocytes and mast cells and restore airway epithelial integrity in bronchial biopsy specimens obtained from mild asthmatic patients. Inhaled budesonide also reduces indices of eosinophil activation in asthma. These effects are likely to result from inhibition of transcription of several cytokines that are over expressed in asthma, in particular the interleukins IL-3, IL-4 and IL-5 and granulocyte macrophage colony stimulating factor (GM-CSF), especially from activated T cells. Glucocorticoids also inhibit plasma exudation through the endothelial barrier of the bronchial vasculature and therefore, their administration leads to a reduction in airway edema. Budesonide inhibits phospholipase A2 activity and by this means reduces the formation of prostaglandins and leukotrienes in the airway.

**Pharmacokinetics**
The preferred analytical method is by high performance liquid chromatography in series with radioimmunoassay, which give a sensitivity of 1 microgram per litre. There is no interference from endogenous steroids.
Absorption from the gastrointestinal tract is probably is probably complete. Oral bio-availability is approximately 10% indicating high pre-systemic metabolism by liver. Studies with 3H-budesonide show no metabolism in lung or nasal application; after inhalation within 5-10 mins; after rectal administration within 1.5 hour. Rectal administration of 2 mg budesonide gave a mean maximal plasma concentration of 3nmol/l (range 1-9 nmol/l). Plasma half-life is approximately 2 hours and the plasma clearance ratio is 0.9 – 1.41/min. The metabolites have minimal biological activities. Inhalation gives a high plasma concentration, 2nmol/l after 500 microgram budesonide, resembling that obtained after intravenous administration. This suggests effective lung deposition and minimal biotransformation in the lung, since poor lung deposition would give a delayed plasma peak as with oral administration. The volume of distribution after intravenous administration is 301 ± 421 and there is little or no entry into the CNS. Plasma protein binding is 86-90% mainly to albumin and not to transcortin. Budesonide is extensively distributed. Tissue distribution has been studied in mouse which showed some placental transfer, but it is not known for humans. No data in concentrations in breast milk in humans is available. Metabolism is more rapid in small children. Metabolic transformation of budesonide in liver is not affected by drugs which inhibits some forms of cytochrome P450 (e.g. cimetidine).

| | |
|---|---|
| Oral absorption | ~100% |
| Pre-systemic metabolism | 90% |
| Plasma half-life mean | 2 hours |
| Volume of distribution | 43 l/kg |
| Plasma protein binding | 86-90% |

**Indication**
Bronchial asthma

**Recommended Dosage**
For oral inhalation. The dosage of BIOSONIDE is individual.
Initially, at the beginning of inhaled corticosteroid therapy, for therapy during periods of severe asthma or when scaling down or withdrawing oral corticosteroids the dosage should be:
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.

**Route of Administration**
For oral inhalation use. To minimize the risk of oropharyngeal candida infection, the patient should rinse their mouth with water after inhaling.

**Contraindication**
Budesonide Pressurized Inhalation is contra-indicated in patients with a history of hypersensitivity to budesonide or any of the components of the drug product.

**Warnings and Precautions**
Budesonide Pressurised Inhalation is not designed to relieve acute symptoms for which an inhaled short-acting bronchodilator is required.

Patients should be made aware of the prophylactic nature of the therapy with inhaled budesonide and it should be taken regularly. Systemic effects of inhaled steroids may occur particularly at high doses for prolonged periods. These effects are must less likely to occur than with oral steroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone density, and cataract and glaucoma in the eyes. It is therefore important that the dose of inhaled corticosteroid is titrated to the lowest at which effective control of asthma is achieved. It is recommended that the height of children receiving prolonged therapy with inhaled steroids be regularly monitored. As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis.

Children on immunosuppressant drugs are more susceptible to infections than healthy children.

Chicken pox and measles can have a more serious and even fatal course in children on immunosuppressant corticosteroids. Replacement of systemic steroid therapy with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by the systemic drug. These should be symptomatically treated with anti-histamine and/or topical steroid preparations.

*For transfer of patients being treated with oral steroids:*
The transfer of oral steroid-dependent patients to Budesonide Pressurised Inhalation and their subsequent management needs special care as recovery from impaired adreno-cortical function due to prolonged systemic steroid therapy may take a considerable time. Gradual withdrawal of the systemic steroid is recommended and in these patients, the possibility of residual impaired adrenal response should always be considered in emergency and elective situations likely to produce stress and appropriate corticosteroid treatment considered.

Pneumonia in patients with COPD
An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies.

There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among inhaled corticosteroid products.

Physicians should remain vigilant for the possible development of pneumonia in patient with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations.

Risk factors for pneumonia in patients with COPD include current smoking status, older age, low body mass index (BMI) and severe COPD.

**Interactions with Other Medications**
a) Interactions:
Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

**Pregnancy and Lactation**
*Pregnancy*
Budesonide has been labeled as pregnancy category B. The possibility of fetal harm is remote if the drug is used pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, budesonide should be used during pregnancy only if clearly needed.

*Lactation*
It is not known whether budesonide is distributed in milk. However, other steroids are distributed in milk hence because of the potential of serious adverse reactions from corticosteroids in nursing infants, a decision should be made whether to discontinue nursing or budesonide taking into account the importance of the drug to the woman.

**Side Effects**

| | |
|---|---|
| Common (>1/100, <1/10):<br>• Mild throat irritation<br>• Candida infection in the oropharynx<br>• Hoarseness of voice<br>• Coughing<br>• Infections and Infestations: Pneumonia (in COPD patients) | Rare (>1/10000, < 1/1000):<br>• Nervousness, restlessness<br>• Behavioural disturbances, depression<br>• Skin bruising<br>• Immediate and delayed hypersensitivity reactions including rash/ contact dermatitis/ urticaria/ angioedema and bronchospasm |

Candida infection in the oropharynx is due to drug deposition. Advising the patient to rinse the mouth with waterafter each dosing will minimize the risk.As with other inhalation therapy, paradoxical bronchospasm may occur invery rare cases.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods.These effects are much lesslikely to occur than with oral corticosteroids. Possible systemic effects include adrenalsuppression, growth retardation in children andadolescents, decrease in bone density, and cataract and glaucoma in the eyes. The effect is probably dependent on dose, exposure time,concomitant and previous steroid exposure and individual sensitivity.

**Symptoms and Treatment of Overdose**
Acute overdose with budesonide inhaler may lead to temporary suppression of adrenal function. This does not necessitate emergency action being taken. In these patients' treatment with budesonide by inhalation should be continued at a dose sufficient to control the asthma. Adrenal function returns in a few days and can be verified by measuring plasma cortisol. Chronic overdosage may lead to adrenal suppression. Monitoring of adrenal reserve may be indicated. Treatment with inhaled budesonide should be continued at a dose sufficient to control asthma.

**Effects on Ability to Drive and Use Machine**
Budesonide has no influence on the ability to drive or use machines.

**Storage Condition**
Store below 30ºC. Do not freeze. Protect from direct sunlight.

**Dosage Form**
Preparation for inhalation in form of Pressurised Metered-Dose Inhaler.

**Packaging Available**
Each canister contains 200 & 300 actuations

**Shelf-life:** 2 years

**Registration No.**
MAL24056098AZ

**Product Registration Holder:**
**Biocare Manufacturing Sdn Bhd**
67, Jalan Gasing, 46000 Petaling Jaya,
Selangor, Malaysia.

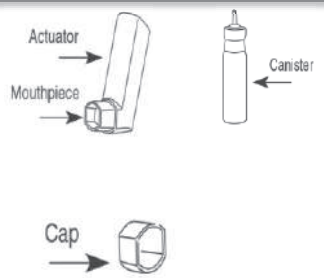
**Manufactured by**
Biocare Manufacturing Sdn. Bhd.
Lot 269, Taman Farmaseutikal,
Bandar Baru Seri Iskandar,
32610 Seri Iskandar, Perak, Malaysia.

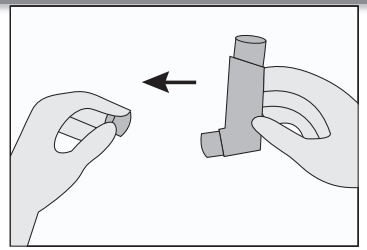
**Distributed by**
Biocare Pharmaceutical (M) Sdn. Bhd.

Date of Revision: 14/5/2024

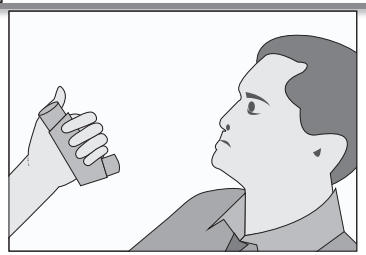
**Preparing your inhaler**
Shake the inhaler 3 - 5 times in an up-down motion before each puff to mix the contents of thw canister. If the device is being used for the first time, prime it by actuating the canister mid-air until an even spray is obtained. For inhalers that are not used for more than 2 weeks, it should be primed before use.

# HOW TO USE YOUR INHALER CORRECTLY

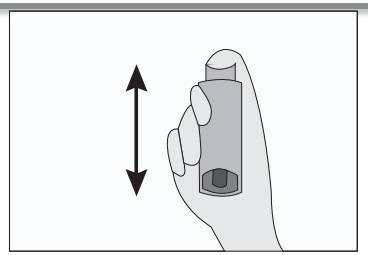


1. Remove the cap from the mouthpiece of the actuator.



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

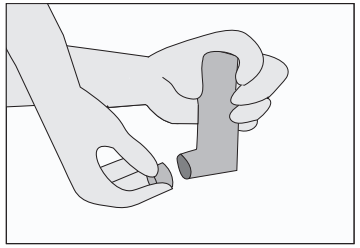


3. Hold the inhaler by placing your index finger on top of the metal canister and thumb on the bottom of the plastic mouthpiece. Shake it well.

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 for one minute, then repeat steps 3 to 6.



7. Replace the mouthpiece cap after each use

## A handy tip for Children

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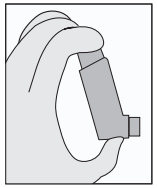

## Cleaning your Inhaler

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.
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**

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.

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

# **BIOSONIDE** 200 mcg HFA Metered Dose Inhaler

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| Oral absorption | ~100% |
| Pre-systemic metabolism | 90% |
| Plasma half-life mean | 2 hours |
| Volume of distribution | 43 l/kg |
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**Indication**
Bronchial asthma

**Recommended Dosage**
For oral inhalation. The dosage of BIOSONIDE is individual.
Initially, at the beginning of inhaled corticosteroid therapy, for therapy during periods of severe asthma or when scaling down or withdrawing oral corticosteroids the dosage should be:
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For oral inhalation use. To minimize the risk of oropharyngeal candida infection, the patient should rinse their mouth with water after inhaling.

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**Warnings and Precautions**
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Patients should be made aware of the prophylactic nature of the therapy with inhaled budesonide and it should be taken regularly. Systemic effects of inhaled steroids may occur particularly at high doses for prolonged periods. These effects are must less likely to occur than with oral steroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone density, and cataract and glaucoma in the eyes. It is therefore important that the dose of inhaled corticosteroid is titrated to the lowest at which effective control of asthma is achieved. It is recommended that the height of children receiving prolonged therapy with inhaled steroids be regularly monitored. As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis.

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a) Interactions:
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**Effects on Ability to Drive and Use Machine**
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**Storage Condition**
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**Dosage Form**
Preparation for inhalation in form of Pressurised Metered-Dose Inhaler.

**Packaging Available**
Each canister contains 200 & 300 actuations

**Shelf-life:** 2 years

**Registration No.**
MAL24056098AZ

BioCare

**Manufactured by**
Biocare Manufacturing Sdn. Bhd.
Lot 269, Taman Farmaseutikal,
Bandar Baru Seri Iskandar,
32610 Seri Iskandar, Perak, Malaysia.

**Product Registration Holder:**
**Biocare Manufacturing Sdn Bhd**
67, Jalan Gasing, 46000 Petaling Jaya,
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**Distributed by**
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Date of Revision: 14/5/2024

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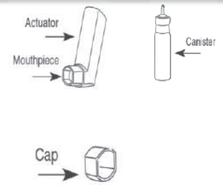
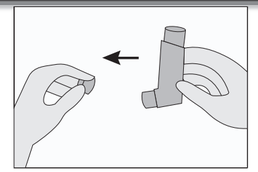
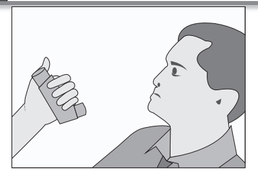
## HOW TO USE YOUR INHALER CORRECTLY

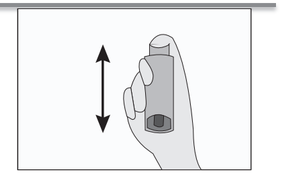


1. Remove the cap from the mouthpiece of the actuator.



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.

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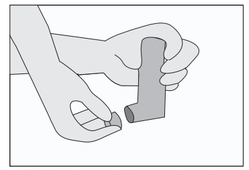

7. Replace the mouthpiece cap after each use

### 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.
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**

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.

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

remark: **Font type: Times New Roman, font size 5.5 pt (text front)**

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|---|---|---|---|---|---|
| ***Sylog Print Systems Sdn Bhd.*** | | | | Date | **14-5-2024** |
| Closed Size | **24cm x 18.5cm** | Customer | **Biocare Manufacturing S/B** | Attn to | **Ms. Thanames** |
| Barcode | | Model Name | **Biosonide 200mcg HFA Metered Dose Inhaler** | Prepared by | **Zul** |
| Colour | **1 color + 1 color printing** | Material | **60gsm simili** | Quantity | **0 pcs** |
| Code | | Finishing | **3 folds** | Artwork No. | **DC 6030-0** |
| | | | | Customer Signature | |