

Brodil[®] HFA

CFC FREE

Inhalation Aerosol Salbutamol

Composition

Brodil[®] HFA Inhaler: Each canister contains 200 measured doses, each containing 100 micrograms of Salbutamol BP.

Pharmacology

Brodil[®] HFA inhaler is a preparation of Salbutamol Sulphate which is CFC free inhaler. Salbutamol is a relatively selective β_2 adrenoceptor stimulant. It is more specific than both isoprenaline and orciprenaline for adrenergic β_2 receptors.

Mechanism of action: Brodil[®] HFA is a sympathomimetic agent which has a highly selective action on β_2 adrenergic receptors in bronchial muscle. It provides short acting (4 to 6 hours) bronchodilation with

fast onset (within 5 minutes) in reversible airway obstruction. β_2 adrenoceptor agonist is used in the treatment of asthma and other forms of diffuse reversible airways obstruction.

Indication

Brodil[®] HFA inhaler is indicated for the treatment and prophylaxis of bronchial asthma and for the treatment of reversible airways obstruction associated with bronchitis and emphysema.

Brodil[®] HFA inhaler may be used to relieve attacks of acute dyspnea and may also be taken prophylactically before exertion or to prevent exercise induced asthma.

Brodil[®] HFA inhaler is suitable for treating bronchospasm in patients with coexisting heart disease or hypertension, including those taking β blockers, because of its selective action on the bronchial receptors and lack of effects on the cardiovascular system. At therapeutic levels, it has little effect on cardiac receptors.

Dose and administration

Route of administration:

Brodil[®] HFA inhaler is administered by the inhaled route only. Shake **Brodil[®] HFA** inhaler well before each spray.

Adults

For the relief of acute bronchospasm and for managing intermittent episodes of asthma: One or two puffs as single dose.

For chronic maintenance or prophylactic therapy: Two puffs three or four times daily.

For prevention of exercise induced bronchospasm: Two puffs should be taken at least 15 minutes before exertion.

Children

For the relief of acute bronchospasm, management of episodic asthma and for prevention of exercise induced bronchospasm: One puff may be administered as single dose.

For routine maintenance and prophylaxis: One puff three or four times daily, increasing if necessary to two puffs three or four times daily.

Elderly

The dosage is the same as that for adults.

Contraindication

Salbutamol inhaler is contraindicated in patient with known hypersensitivity to salbutamol or any components of this product. Although intravenous salbutamol and occasionally salbutamol tablets are used in the management of premature labour uncompliated by conditions such

as placenta praevia, ante-partum hemorrhage or toxemia of pregnancy, salbutamol inhaler preparations are not appropriate for managing premature labour.

Warning and precaution

The management of asthma should be normally a stepwise program and patient response should be monitored clinically and by lung function test. Increasing use of short acting inhaled β_2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted. Patients' inhaler technique should be checked to make sure that aerosol actuation is synchronized with inspiration of breath for optimum delivery of the drugs to the lungs. Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis. In the event of previously effective dose of salbutamol inhaler failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken.

Side effects

Mild tremor and headache have been rarely reported. These usually disappear with continuous treatment. There have been very rare reports of transient muscle cramp. Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse have been reported very rarely. 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 should be instituted.

Use in pregnancy and lactation

Pregnancy: Salbutamol is known to cross the placental barrier in humans. Safety for use in pregnancy has not been demonstrated, therefore the drug should not be used in pregnant women or those likely to become pregnant, unless the expected benefit outweighs any potential risk. Salbutamol tablets are used in the management of uncomplicated premature labour, salbutamol presentations should not be used for threatened abortion during the first or second trimesters of pregnancy. Intravenous salbutamol is contraindicated in cases of ante-partum hemorrhage because of the risk of further hemorrhage from

an atonic uterus and there is the risk of the same problem arising inadvertently in asthmatics using salbutamol. Profuse uterine bleeding following spontaneous abortion has been reported after the use of salbutamol. Special care is required in pregnant diabetic women.

Lactation: As salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefit to the mother is greater than any possible risk to the infant.

Drug interaction

Drug interaction with drug: Salbutamol should be administered with caution to patients being treated with monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants, since the action of salbutamol on the vascular system may be potentiated. The effects of salbutamol are inhibited by β antagonists such as propranolol. Other sympathomimetic aerosol bronchodilator should not be used concomitantly with salbutamol. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects. Treatment with diuretics may augment the hypokalemia that occurs with large doses of salbutamol.

Drug interaction with food and others: Not applicable.

Overdose

As with all sympathomimetic aerosol medications, cardiac arrest and even death may be associated with abuse. The preferred antidote for overdose with salbutamol inhaler is cardioselective β -blocker, such as metoprolol tartrate. But β -blockers should be used with caution in patients with a history of bronchospasm. Dialysis is not appropriate treatment for overdose of salbutamol inhalation aerosol.

Storage

Store in a cool (below 30°C) and dry place protected from light. Keep away from the reach children. Keep away from eyes. Do not puncture, break or incinerate pressurized canister even when apparently empty.

Packing

Brodil[®] HFA inhaler: Each canister contains 200 metered doses, each actuation delivers Salbutamol BP (as Sulphate) 100 micrograms.

® Registered Trade Mark

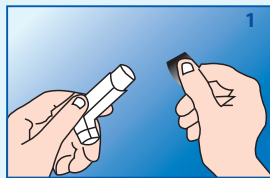


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HOW TO USE YOUR INHALER CORRECTLY

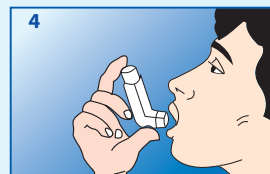
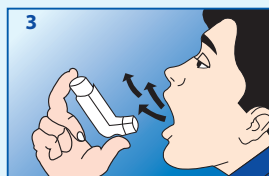
Before using your inhaler, please read this part and follow the instructions carefully

(আপনার ইনহেলার ব্যবহারের আগে এই অংশটি পড়ুন এবং সতর্কতার সাথে এই ব্যবহারবিধি অনুসরণ করুন।)



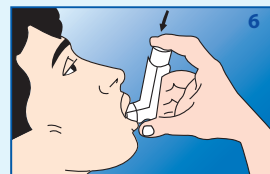
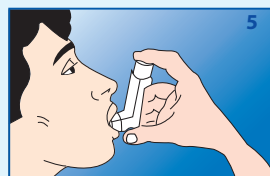
Remove the mouthpiece cover and check the mouthpiece thoroughly to see that it is clean. Then shake the inhaler vigorously. (Pic-1 & 2)

কভারটি প্রথমে সরতে হবে এবং সতর্কতার সাথে এটি পরিষ্কার কিনা পরীক্ষা করতে হবে। অতঃপর ইনহেলারটি ভাল ভাবে ঝাঁকতে হবে। (চিত্র-১ ও ২)



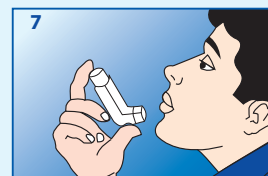
Hold the inhaler as shown between index finger and thumb. Breathe out gently through your mouth and immediately place the mouthpiece in your mouth (Do not bite it). (Pic-3 & 4)

চিত্রের মত তর্জনী ও বুড়ো আঙ্গুলের মধ্যে ইনহেলারটিকে ধরতে হবে। মুখ দিয়ে ধীরে ধীরে বাতাস বের করে দিতে হবে এবং ইনহেলারের নিঃসরণ দ্বারা মুখের মধ্যে দাঁতের ফাঁকে স্থাপন করতে হবে (কামড়ানো যাবে না)। (চিত্র-৩ ও ৪)



Grip the mouthpiece firmly with your lips. Tilt your head slightly backwards. Start breathing in slowly through your mouth. At the same time press the canister as shown, to release one dose while continuing to breathe in steadily and deeply. (Pic-5 & 6)

ঠোঁট দিয়ে শক্তভাবে ইনহেলার ধরতে হবে। মাথা সামান্য পেছন দিকে হেলাতে হবে। মুখ দিয়ে ধীরে ধীরে শ্বাস গ্রহণ করতে হবে এবং একই সময়ে ক্যানিস্টারটিকে চাপ দিতে হবে। এভাবে ধীরে ধীরে গভীরভাবে শ্বাস নেয়ার সময় একটি মাত্রা নিতে হবে। (চিত্র-৫ ও ৬)



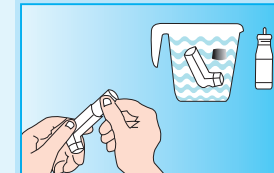
Remove the inhaler from your mouth. Hold the breath at least for 10 seconds or as long as it is comfortable. Breathe out slowly. (Pic-7 & 8)

ইনহেলারটিকে মুখ থেকে সরিয়ে ফেলতে হবে। ১০ সেকেন্ড অথবা যতক্ষণ সম্ভব শ্বাস বন্ধ করে রাখতে হবে। অতঃপর ধীরে ধীরে শ্বাস ছাড়তে হবে। (চিত্র-৭ ও ৮)

If another dose is required, wait for at least 1 minute and repeat the whole process. After use, place the cover to close the mouthpiece.

যদি একাধিক মাত্রা গ্রহণের দরকার হয় তবে কমপক্ষে ১ মিনিট অপেক্ষা করার পর পুরো পদ্ধতিটি পুনরাবৃত্তি করতে হবে। ব্যবহারের পর কভারটি যন্ত্রটির মুখের সঠিক জায়গায় স্থাপন করতে হবে।

How to clean your inhaler



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 water but do not put the metal canister into water.

3. Leave to dry in warm place, avoid excessive heat.

4. Replace the canister and the mouthpiece cover correctly.

**CLEAN YOUR INHALER
AT LEAST ONCE A WEEK**

কিভাবে আপনার ইনহেলার পরিষ্কার করবেন

১. সাবধানে ধাতব ক্যানিস্টারটিকে প্লাস্টিকের বহিরাবরণ থেকে মুক্ত করুন, মাউথপিস কভারটি খুলে ফেলুন।

২. প্লাস্টিকের বহিরাবরণ এবং মাউথপিস কভারটিকে গরম পানি দিয়ে ধুয়ে ফেলুন, কিন্তু ধাতব ক্যানিস্টারটিকে কখনোই পানিতে ভেজাবেন না।

৩. শুকানোর জন্য কোন শুষ্ক স্থানে রাখুন, অতিরিক্ত গরম জায়গায় রাখবেন না।

৪. ক্যানিস্টার এবং মাউথপিস কভারটিকে সঠিক জায়গায় স্থাপন করুন।

প্রতি সপ্তাহে অন্তত একবার আপনার ইনহেলার পরিষ্কার করুন।

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