

Rx

**BECLOMETHASONE
DIPROPIONATE**

BECLOCORT-100
100 mcg/ Actuation
Metered Dose Inhaler
Anti-asthma

FORMULATION:

Each actuation contains:
Beclomethasone Dipropionate.....100 mcg

PRODUCT DESCRIPTION:

Aluminium can contains solution for inhalation is supplied in crimping with a metering valve and actuator, which are held under pressure with suitable propellants.

PHARMACOLOGY:

Beclomethasone Dipropionate is a synthetic glucocorticoid. It has many important functions, including control on inflammatory responses. When Beclomethasone is inhaled into the lungs. It is absorbed into the cell of the lungs and airways. By preventing the inhalation and excess mucus formation, Beclomethasone makes it easier to breathe and helps prevent asthma attacks. Use of Beclomethasone inhaler also reduces the potential for side effects occurring in other parts of the body, as the amount absorbed into the blood through the lungs is lower than if it is taken by mouth. Inhaled glucocorticoids (GCs) can significantly decrease bronchial hyperreactivity, as effective oral/systemic GCs in preventing relapses. Generally, GC therapy even though some inhaled GCs are systematically absorbed from oral, respiratory and GIT mucosa. This may be due to rapid metabolism in the local tissues or enhanced 1st pass effect or both.

INDICATION:

For maintenance therapy of mild, moderate and severe persistent asthma.

CONTRAINDICATIONS:

Hypersensitivity to the corticosteroid or its components.

PRECAUTIONS:

1. Instruct patients on proper use of inhalers, including the need for continuous use; instruct patients to gargle and spit out washing after inhalation of drug.
2. Use spacer or extender tube on metered dose inhaler (MDI) to lessen impaction of large size particulate mist

on buccal cavity, while enhancing delivery of finer particles of inhaled steroids while enhancing delivery of finer particles of inhaled steroids into the distal airways.

3. May premedicate with selective B2-agonist to lessen paradoxical bronchospasm and cough.
4. Once patient has been stable for some time, taper inhaled steroids gradually in stepwise fashion to the lowest possible side to maintain control.
5. Monitor growth in children. Inhaled corticosteroids have been shown in some studies to cause a reduction in growth velocity in the paediatric age group.
6. Be alert for any possible systemic adverse effects.
7. Patients with persistent severe asthma on long term systemic steroids and who are started on high dose inhaled steroids should be weaned gradually from systemic steroids to let hypothalamo-pituitary-adrenal (HPA) axis recover. Inhaled steroids may not be able to provide enough systemic level to prevent steroid withdrawal syndrome.

ADVERSE REACTIONS:

Local adverse effects are more common than systemic effects, such as hoarseness, or candidiasis, coughing and reflex bronchoconstriction. These can be minimized by premedicating with B2-agonist, using spacer of tube extender with MDI, Instructing patients to gargle after inhalation, Systemic adverse effects associated with systemic steroid use may occur even with inhaled steroids and the potential for growth suppression remains. Hypersensitivity reactions: urticarial, angioedema, rashes.

REPORTING OF SUSPECTED ADVERSE REACTIONS:

To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

PREGNANCY RISK CATEGORY B:

Use in pregnancy only if potential benefit outweighs potential risk to fetus especially when there has been no clinical response to first line inhaled steroid in a pregnant asthmatic. There had been increased incidence of congenital malformation associated

with Beclomethasone use.

DOSAGE AND ADMINISTRATION:

Inhalation (as Dipropionate): with appropriate accompanying dispenser:

Breath Actuated MDI:

50 mcg/dose x 200 doses

100 mcg/dose x 200 doses

250 mcg/dose x 200 doses

Management of chronic asthma

Adults & children over 12 years: 100-400 mcg twice daily. Maximum 1000 mcg twice daily

Children (5-12 years): 100-200 mcg twice daily. Maximum 200-400 mcg twice daily.

Prophylaxis of asthma

Adults & children over 12 years: 50-200 mcg twice daily. Increased if necessary to maximum 400 mcg twice daily.

Children (5-12 years): The usual starting dose is 100 mcg twice daily. Depending on the severity of asthma, the daily dose may be increased up to 400 mcg administered in 2-4 divided doses. When patients symptoms remain under satisfactory control, the dose should be titrated to the lowest dose at which effective control of asthma is maintained.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:

Store at temperature not exceeding 30°C.

FDA Registration No.: DR-XY44855

Date of Initial Authorization: 20 November 2020

Date of Revision of package insert: 20 January 2022

AVAILABILITY:

Aluminium Can Crimped with metering valve and actuator (Box of 1's)

Manufactured by:
ARISTOPHARMA LTD.
Plot # 14-22, Road # 11 & 12, Shampur-Kadamtali I/A.
Dhaka-1204, Bangladesh.

Imported and Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave, Phase III, BF Homes
Parañaque City.

20004390/02

Important information for the patients

HFA Inhaler

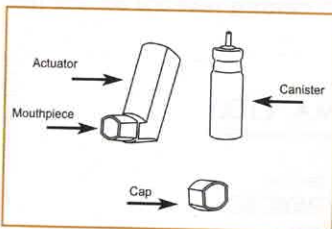
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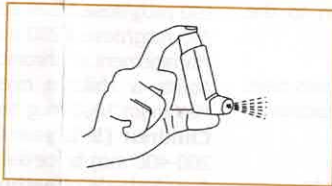
CFC
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Parts of an inhaler



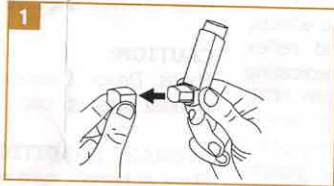
How to use your inhaler correctly?

Test your inhaler

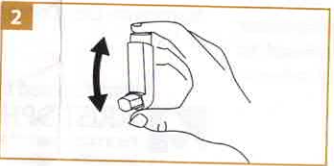


Before using your Inhaler for the first time, or if it has not been used for a week or more, shake it well and then "test fire" it, i.e. release one puff into the air.

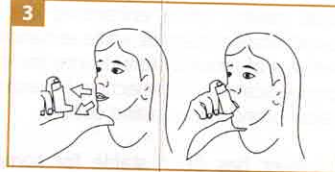
Using your inhaler



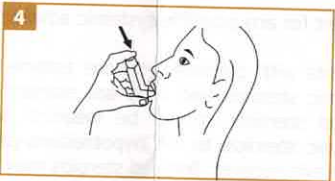
1. Remove the cap from the mouthpiece of the actuator. Make sure there is nothing in the mouthpiece before use.



2. Hold canister as illustrated in figure. Shake the canister vigorously for at least 10 seconds.



3. Breathe out gently as you can and immediately place the mouthpiece in your mouth between your teeth. Do not bite it.



4. Tilt your head slightly backward. Start breathing slowly through your mouth. At the same time press down firmly at the top of the canister to release medicine. Continue to breathe in steadily & deeply.



5. Remove the inhaler from your mouth & hold your breath for 10 seconds or as long as it is comfortable. Then breathe out gently. If you take a second inhalation, you should wait for at least one minute before repeating steps 3 & 4.



6. After use, replace the mouthpiece cap.

Important

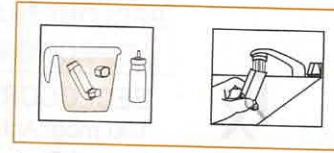


Do not rush steps 4 and 5. It is important that you start to breathe in as slowly as possible just before releasing the dose. Practice in front of the mirror for the first few times. If you see "mist" coming from the top of the inhaler or the sides of your mouth, start again from step 2. This escaping mist indicates incorrect technique.

How to clean your inhaler?



1. Remove the metal canister from the actuator (plastic casing) of the inhaler & remove the mouthpiece cap.

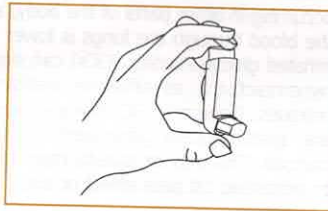


2. Immerse the actuator (plastic casing) & the mouthpiece cap in warm water for few minutes and then rinse them under running water. But do not put the metal canister into water.

3. Leave actuator & mouthpiece cap to dry in warm place, avoid excessive heat.

4. Replace the canister and the mouthpiece cap correctly.

Your inhaler should be cleaned at least once a week.



Tips for children

Children & others who have weaker hands may have difficulty pressing down on the top of the canister with just one hand. They can use both hands to make their inhaler work.