

## A long horizontal double-headed arrow, consisting of a thick black line with arrowheads at both ends, spanning most of the width of the page.

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Beclometasone Pressurised Inhalation BP  
100 mcg/actuation

Beclometasone inhaler

There is no experience of this product in pregnancy and lactation in humans, therefore the product should only be used if the expected benefits to the mother are thought to outweigh any potential risk to the foetus or neonate.

ICONGRAPHICS CODE

**PHARMACODE:**

GRAIN DIRECTION

SAME SIZE ARTWORK  
LEAFLET: 225 mm x 270 mm  
FOLDING SIZE: 38 mm x 135 mm

Beclometasone dipropionate

There is inadequate evidence of safety in human pregnancy. In animals, systemic administration of relatively high doses can cause abnormalities of foetal development including growth retardation and cleft palate. There may therefore be a very small risk of such effects in the human foetus. However, inhalation of beclometasone dipropionate into the lungs avoids the high level of exposure that occurs with administration by systemic routes.

The use of beclometasone dipropionate in pregnancy requires that the possible benefits of the drug be weighed against the possible hazards. The drug has been in widespread use for many years without apparent ill consequence.

It is probable that beclometasone dipropionate is excreted in milk. However, given the relatively low doses used by the inhalation route, the levels are likely to be low. In mothers breast feeding their baby the therapeutic benefits of the drug should be weighed against the potential hazards to mother and baby.

UNDESIRABLE EFFECTS

Adverse events are listed below by system class and frequency. Frequencies are defined as: very common ≥ (1/10), common ≥ 1/100 and <1/10), uncommon ≥ 1/1,000 and <1/100), rare ≥ 1/10,000 < 1/1,000) very rare (≥ 1/10,000) and not known (cannot be estimated from available data).

| System Organ Class                            | Adverse Event                                                                                                                                                      | Frequency   |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Infections & Infestations                     | Candidiasis of the mouth and throat.                                                                                                                               | Very Common |
| Immune System Disorders                       | Hypersensitivity reactions with the following manifestations:                                                                                                      |             |
|                                               | Rashes, urticaria, pruritis, erythema and bruising                                                                                                                 | Uncommon    |
|                                               | Oedema of the eyes, face, lips and throat                                                                                                                          | Very Rare   |
|                                               | Respiratory symptoms (dyspnoea and/or bronchospasm)                                                                                                                | Very Rare   |
|                                               | Anaphylactoid/anaphylactic reactions                                                                                                                               | Very Rare   |
| Endocrine Disorders                           | Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma | Very Rare   |
| Psychiatric Disorders                         | Psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children)                                       | Unknown     |
| Respiratory, Thoracic & Mediastinal Disorders | Hoarseness/throat irritation                                                                                                                                       | Common      |
|                                               | Paradoxical bronchospasm                                                                                                                                           | Very Rare   |

As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. Beclometasone Dipropionate should be discontinued immediately, the patient assessed and, if necessary, alternative therapy instituted.

Candidiasis of the mouth and throat (thrush) occurs in some patients especially at higher dose. It may be recommended to rinse the mouth with water immediately after inhalation. Symptomatic candidiasis can be treated with topical anti-fungal therapy.

Inhaled corticosteroids may have some systemic effects, particularly at high doses prescribed for prolonged periods. These effects are adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density leading to osteoporosis, cataract and glaucoma and easy bruising of the skin, lower respiratory tract infections, including pneumonia, in older patient with chronic obstructive pulmonary disease (COPD).

OVERDOSAGE

Acute overdosage is unlikely to cause problems. The only harmful effect that follows inhalation of large amounts of the drug over a short time period is suppression of HPA function. Specific emergency action need not be taken. Treatment with Beclometasone inhaler should be continued at the recommended dose to control the asthma; HPA function recovers in a day or two.

If excessive doses of beclometasone dipropionate were taken over a prolonged period a degree of atrophy of the adrenal cortex could occur in addition to HPA suppression. In this event the patient should be treated as steroid dependent and transferred to a suitable maintenance dose of a systemic steroid such as prednisolone. Once the condition is stabilised, the patient should be returned to Beclometasone inhaler.

STORAGE AND HANDLING INSTRUCTIONS

Store below 30°C. Do not freeze.

MAL14055135AZ

BRU20022785P

PACKAGING INFORMATION

Beclometasone Pressurised Inhalation BP 100 µg/actuation, 200 MD

SHELF LIFE

24 months

Date of Revision: 02/07/2024

INSTRUCTIONS FOR PATIENT  
FOR USING THE INHALER WITHOUT SPACER

Important: Follow instructions carefully.

Shake the inhaler well immediately before each use.

Testing your inhaler:

If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of two days, "test spray" the inhaler. Spray the inhaler 4 times into the air. (see pic no. 1)



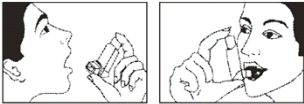
1

Remove the cap from the mouthpiece; the strap on the cap will stay attached to the actuator. If the strap is removed from the actuator, the mouthpiece should be inspected for the presence of foreign objects before each use. 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 dose. (see pic no. 4)



4

Remove the inhaler from your mouth and hold breath for 10 seconds or for as long as it is comfortable. Breathe out slowly. (see pic no. 5)



5

Note:

Rinse your mouth or gargle with water after inhaling each dose. This is likely to reduce the soreness that may be caused by the drug. If another dose is required wait for at least one minute and repeat steps 2 through 5 for each inhalation prescribed by your Physician. 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

For Children:

Children should use the inhaler under adult supervision, as instructed by the Physician. (see pic no. 8)



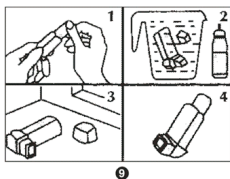
8

Cleansing:

Clean the inhaler at least once a day.

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.
5. Store the spacer by hygienically.

Discard the canister after using the labeled number of inhalation.



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Product Registration Holder

Glenmark Pharmaceuticals (Malaysia) Sdn Bhd (660397-W)  
D-31-02, Menara Suezcap 1,  
No. 2, Jalan Kerinchi,  
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Manufactured by:  
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Baddi-Nalagarh Road, Tehsil Baddi,  
Distt. Solan (H.P.) 173205, India

MY  
PE00000

ICONGRAPHICS CODE:

PANTONE SHADE



PANTONE  
BLACK  
PROCESS C

Supersedes  
Artwork Code:

PHARMACODE: