decomit

HFA Inhaler

50 mcg/dose, HFA Metered
Dose Inhaler
Beclometasone Dipropionate BP
Inhalation Aerosol

Description
It is a clear solution of Beclometasone dipropionate & Ethanol which is filled into aluminium can fitted onto a valve. The propellant (Tetrafluotoethane HFA) is then filled into the can through valve. The can fitted with valve labeled, then again fitted with an actuator and dust cap. This is then packed inside an inner carton with leaflet inside.

Indications and Usage
Decomit HFA is indicated for the prophylactic management of mild, moderate, or severe asthma.

Mechanism of action
Beclometasone dipropionate is a pro-drug with weak glucocorticoid receptor binding affinity. It is extensively hydrolysed via esterase enzymes to the active metabolite beclometasone-17-monopropionate (B-17-MP), which has potent topical anti-inflammatory activity.

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 characterised 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 tritiated 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

Adult : 200 mcg twice a day . Alternatively, the total daily dose may be administered as 3 or 4 divided doses. In severe cases, dosage may be started at 600-800 mcg/day and subsequently reduced when the patient begins to respond.

Children : 1 or 2 inhalations (50-100 mcg/day) should be given 2, 3 or 4 times daily accordingly to the response.

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

Precautions
Patients should be instructed in the proper use of the inhaler, and their technique checked, to ensure that the drug reaches the target areas within the lungs. They should also be made aware that Decomit has to be used regularly every day for optimum benefit. Patients should be made aware of the prophylactic nature of therapy with Decomit and that they should be used regularly, even when they are asymptomatic.
Decomit is not designed to relieve acute asthma symptoms for which an inhaled short-acting bronchodilator is required. Patients should be advised to have such rescue medication available.
Severe asthma requires regular medical assessment, including lung-function testing, as patients are at risk of severe attacks and even death.
Increasing use of bronchodilators, in particular short-acting inhaled beta2 agonists to relieve symptoms indicates deterioration of asthma control. If patients find that short acting relief bronchodilator treatment becomes less effective or they need more inhalations than usual, medical attention must be sought.
In this situation, patients should be reassessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid) considered. Severe exacerbations of asthma must be treated in the normal way.
Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important therefore 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 corticosteroid, if possible, to the lowest dose at which effective control of asthma is maintained. In addition, consideration should be given to referring the patient to a paediatric respiratory specialist.
Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.
Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than recommended doses, may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.
Lack of response or severe exacerbations of asthma should be treated by increasing the dose of inhaled beclometasone dipropionate and, if necessary, by giving a systemic steroid and/or antibiotic if there is an infection, and by use of beta-agonist therapy.
For the transfer of patients being treated with oral corticosteroids:
The transfer of oral steroid-dependent patients to Decomit and their subsequent management needs special care as recovery from impaired adrenocortical function, caused by prolonged systemic steroid therapy, may take a considerable time.
Patients who have been treated with systemic steroids for long periods of time or at a high dose may have adrenocortical suppression. With these patients adrenocortical function should be monitored regularly and their dose of systemic steroid reduced cautiously.
After approximately a week, gradual withdrawal of the systemic steroid is commenced. Decrements in dosages should be appropriate to the level of maintenance systemic steroid, and introduced at not less than weekly intervals. For maintenance doses of prednisolone (or equivalent) of 10mg daily or less, the decrements in dose should not be greater than 1mg per day, at not less than weekly intervals. For maintenance doses of prednisolone in excess of 10mg daily, it may be appropriate to employ cautiously, larger decrements in dose at weekly intervals.
Some patients feel unwell in a non-specific way during the withdrawal phase despite maintenance or even improvement of the respiratory function. They should be encouraged to persevere with Decomit and withdrawal of systemic steroid continued, 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 steroid during periods of stress, e.g. 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.
Treatment with Decomit should not be stopped abruptly.
As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis.

Interactions
Beclometasone 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. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

Pregnancy and Lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human fetus. It should be noted, however, that the fetal changes in animals occur after relatively high systemic exposure. Decomit delivers the drug directly to the lungs by the inhaled route and so avoids the high level of exposure that occurs when corticosteroids are given by systemic routes.

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

Breast-feeding

No specific studies examining the transference of beclometasone dipropionate into the milk of lactating animals have been performed. It is reasonable to assume that beclometasone dipropionate is secreted in milk, but at the dosages used for direct inhalation there is low potential for significant levels in breast milk. The use of beclometasone dipropionate in mothers breast feeding their babies requires that the therapeutic benefits of the drug be weighed against the potential hazards to the mother and baby.

Side Effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (1/10), common (1/100 and <1/10), uncommon (1/1000 and <1/100), rare (1/10,000 and <1/1000), very rare (<1/10,000) including isolated reports and not known (cannot be estimated from the available data). Very common, common and uncommon events were generally determined from clinical trial data. The incidence in placebo and comparator group has not been taken into account in estimation of these frequencies. Rare and very rare events were generally determined from spontaneous 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.	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)	Not known
Eye disorders	Vision blurred (see also section 4.4)	Not known
Respiratory, Thoracic & Mediastinal Disorders	Hoarseness/throat irritation, cough	Common
	Paradoxical bronchospasm	Very Rare
	Eosinophilic pneumonia	Not Known
Skin and subcutaneous tissue disorders	Easy bruising, skin thinning	Not known

Candidiasis of the mouth and throat (thrush) occurs in some patients, the incidence increasing with doses greater than 400 micrograms of beclometasone dipropionate per day. Patients with high blood levels of *Candida precipitins*, indicating a previous infection, are most likely to develop this complication. Patients may find it helpful to rinse their mouth thoroughly with water after using the inhaler. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst still continuing with Decomit treatment.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma (see 4.4 Special Warnings and Precautions for Use).

In some patients inhaled beclometasone dipropionate may cause hoarseness, cough, throat irritation and sore throat. It may be helpful to rinse the mouth out with water immediately after inhalation.

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. The beclometasone dipropionate preparation should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted.

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 beclometasone dipropionate in daily doses in excess of 1,500 micrograms 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.

Pharmaceutical Precautions

Store below 30°C. Keep out of the reach of children.

Shelf Life

2 years

Commercial Pack

Decomit 50 HFA Inhaler: Each canister contains 200 metered doses, each containing 50 mcg of beclometasone dipropionate BP. It does not contain CFC as propellant.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.
126, Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh
291122

Product Registration Holder

BEXIMCO HEALTHCARE MALAYSIA SDN. BHD
22-2, Jalan 1/64, Off Jalan Kolam Air/Jalan Ipoh, 51200, Kuala Lumpur, Malaysia

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Important information for the patients

Before using your Decomit HFA inhaler, please read this leaflet carefully and follow these instructions to get the results you expect from this prescribed medication.

What does it mean when we say "Decomit is CFC - FREE"?

The CFC propellant that was once in Decomit inhaler has now been replaced with a more environment friendly 'non-CFC' propellant, called HFA.

If you have used the old (CFC-containing) Decomit, you may notice a difference in the taste, and a softer feel of the 'puff'. Even though you may feel that the puff is softer, the amount of Decomit in each puff is the same as in the old CFC Decomit.

Prime your Decomit HFA Inhaler

Decomit HFA inhaler should be primed before using it for the first time. You should also prime your inhaler when the inhaler has not been used for more than 10 days.

What do we mean by 'Priming' of the inhaler?

When using your new inhaler for the first time or if it has not been used for 10 days or more, you should prime your inhaler before use. This is known as priming.

How to prime the inhaler?

To prime simply release two actuations into the air away from your *face.*

Why priming of the inhaler is important

Priming ensures that your inhaler delivers the correct dose. Once primed, your inhaler is ready to use and deliver the correct amount of medicine.

HOW TO USE YOUR INHALER CORRECTLY

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.

2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.

3. Shake the inhaler well to ensure any loose objects are removed and the contents of the inhaler are evenly mixed.

4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.

5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.

6. Just after starting to breathe in through your mouth press down on the top of the inhaler to release AZMASOL while still breathing in steadily and deeply.

7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.

8. If you are to take further puffs keep the inhaler upright and wait about half a minute before repeating steps three to seven.

9. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

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.

How to clean your Inhaler?

1. Remove the metal canister from the plastic casing of the inhaler and remove the mouth piece cover.
2. Rinse the actuator thoroughly with warm water.
3. Dry the actuator thoroughly inside and outside.
4. Replace the metal canister and the mouth piece cover
5. Do not put the metal canister in water.

Your inhaler should be cleaned at least once a week

Cleaning your Inhaler

Keeping the plastic actuator clean is very important to prevent medicine build up 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

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
- Pressurised canister, do not puncture, break or incinerate even when apparently empty
- Avoid storage in sunlight or heat
- Store below 30°C
- Avoid eye contact
- Keep away from children