

# DECOMIT HFA METERED DOSE INHALER

Beclometasone Dipropionate 50mcg and 100 mcg

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## What Decomit<sup>®</sup> is used for

The active component of Decomit<sup>®</sup> is Beclometasone Dipropionate BP, an anti-inflammatory corticosteroid. It helps to prevent asthma in people who need regular treatment. This is why it is sometimes called 'preventer'.

## How Decomit<sup>®</sup> works

Decomit<sup>®</sup> works by reducing swelling and irritation in the lungs. It is a pressurized, metered-dose aerosol intended for oral inhalation only. It is an environment friendly inhaler.

## Before you use Decomit<sup>®</sup>

- When you must not use it

Do not use Decomit<sup>®</sup> if you are allergic (hypersensitive) to:

- Beclometasone Dipropionate
- any of the other ingredients of Decomit<sup>®</sup>

Do not use Decomit<sup>®</sup> if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before using Decomit<sup>®</sup>.

## Pregnancy and lactation

Do not take Decomit<sup>®</sup> if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Decomit<sup>®</sup> if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Check with your doctor, nurse or pharmacist before taking your medicine if:

- you have ever been treated for tuberculosis (TB)
- you are using Beclomethasone at the same time as taking steroid tablets. Also if you have just finished taking steroid tablets.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Decomit<sup>®</sup>.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Decomit<sup>®</sup> HFA metered dose inhaler contains a small amount of ethanol. There is a theoretical potential for interaction in particularly sensitive patients taking disulfiram or metronidazole.

## How to use Decomit<sup>®</sup>

- How much to use

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.

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

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Decomit<sup>®</sup> for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Overdosage may lead to suppression of adrenal gland (adrenal glands do not produce adequate amounts of steroid hormones).

## While you are using it

- Things you must do

Your inhaler should be cleaned at least once a week.

If the inhaler is new or has not been used for three days or more, one puff should be released into the air.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Decomit<sup>®</sup>.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Decomit® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

When giving to children, it is recommended that the height of children receiving long term treatment of inhaled corticosteroids is regularly monitored. It is important to use the lowest dose at which effective control of asthma is maintained.

Pressurized canister - do not puncture, break or incinerate even when apparently empty.

**Side effects**

Like all medicines, Decomit® can cause side effects, although not everybody gets them. If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away. You may need urgent medical treatment.

- Hypersensitivity reactions including rashes, urticaria (raised, itchy rash on the skin), itching, erythema (redness of the skin) and oedema (swelling) of the eyes, face, lips and throat.
- Your breathing or wheezing gets worse straight after using your inhaler.
- Adrenal suppression
- Growth retardation in children and adolescents
- Decrease in mineral bone density
- Cataract and glaucoma (increased pressure in the eye)

Other side effects include fungal infection of the mouth, hoarseness or throat irritation. This can be overcome by rinsing the mouth out with water immediately after inhalation.

Visit your doctor or pharmacist immediately if you experience any side effects listed or not listed here after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

**Storage and Disposal of Decomit®**

- Storage

Keep out of the reach and sight of children. Avoid storage in direct sunlight or heat.  
Store below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

It is a clear solution of Beclometasone dipropionate & Ethanol which is filled into aluminium can fitted onto a valve. The propellant (Tetrafluoroethane HFA, 134a) 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.

- Ingredients

- Active ingredient  
Beclometasone Dipropionate BP  
50mg or 100mcg
- Inactive ingredients
  - Dehydrated Alcohol
  - Tetra-fluoro ethane (HFA 134a)

- MAL number(s):

Decomit 50 mcg: MAL09082797A  
Decomit 100 mcg: MAL09082798A

**Manufacturer**

Beximco Pharmaceuticals Ltd  
126, Kathaldia, Auchpara,  
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**Product Registration Holder**

Vitamode Sdn.bhd  
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**Date of revision**

28/1/2015

**Serial Number**

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