BECLOTEN® INHALER 100MCG

Beclometasone dipropionate (100mcg/actuation)

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What Becloten® Inhaler is used for

Becloten® Inhaler contains *beclometasone dipropionate,* which is one of a group of medicines known as glucocorticoid. Becloten® Inhaler is used in the prophylactic management of asthma.

How Becloten® Inhaler works

The anti-inflammatory effect of *beclometasone dipropionate* plays an important role in the efficacy of *beclometasone dipropionate* in controlling symptoms and improving lung function in asthma. It is a pressurised metered-dose spray is for oral inhalation use only. Becloten® inhaler is not indicated for the immediate relief of asthma attacks.

Before you use Becloten® Inhaler

- When you must not use it

Do not use Becloten® Inhaler if you are allergic (hypersensitive) to:

a) *Beclometasone dipropionate*
b) any of the other ingredients of Becloten® Inhaler.

Do not use Becloten® Inhaler if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before using Becloten® Inhaler.

- Before you start to use it

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

a) you are suffering from active or latent pulmonary tuberculosis.
b) your asthma seems to be getting worse. Perhaps you are feeling wheezy and short of breath than usual, your 'reliever' inhaler seems to be less effective, you require more puffs from your 'reliever' inhaler than usual, or you do not seem to be getting better. Your doctor may need to increase the dose of your steroid inhaler or give you a course of steroid tablets or change your treatment altogether. If you have had an infection in your chest your doctor may prescribe a course of antibiotics.
c) when transferring from steroid tablets to an inhaler you find that, even if your chest is getting better, you feel generally unwell, you develop a rash, eczema or a runny nose and sneezing (rhinitis). Do not stop treatment with your inhaler unless your doctor tells you to.

Important points to remember while you are using this medicine:

a) Your doctor may prescribe this inhaler to replace steroid tablets, which may mean for a short time you have to take both medicines. It is important to follow your doctor's advice. Whilst you are reducing the number of steroid tablets that you take you may feel generally unwell even though you can breathe as well as normal or better. If you have other allergies, you may find that stopping your steroid tablets makes them worse. If this happens keep using your inhaler and tell your doctor.
b) If you have been treated for a long time with high doses of inhaled steroid, you may require a course of steroid tablets. Your doctor will decide if you need any extra steroid treatment and will also advise you as to how long you need to take the course of steroid tablets and how you should reduce these as you get better.
c) You should have been given a steroid card with this inhaler, if you have not, please ask your pharmacist for one. Make sure you carry your steroid card with you at all times until your doctor decides that it is no longer necessary.
d) Visit your doctor regularly for a review of your condition.
e) If you have to go to hospital, remember to take all your inhalers and other medicines including those bought without prescription with you.
f) Inhaled steroid treatment should not be stopped abruptly.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Becloten® Inhaler.

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- *Taking other medicines*
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription. Some medicines may increase the effects of Becloten® Inhaler and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

How to use Becloten® Inhaler
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

- *How much to use*
The recommended dose in adults is as follows:

For mild to moderate asthma:
50µg to 200µg twice daily
For more severe asthma:
doses up to 400µg twice daily.
Maximum recommended daily dose: 800µg
In children aged five years and over the recommended dose is 50µg twice daily.

Becloten® Inhaler must be used on a regular basis even when patients are asymptomatic. When patients' symptoms remain satisfactorily controlled the dose of Becloten® Inhaler can be gradually reduced to the minimum effective dose to maintain control.
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 Becloten® Inhaler 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)*
It is important that you take your dose as stated on the pharmacist's label, or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice. 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).
Pregnancy, breast-feeding and fertility:
If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking this medicine.

While you are using it
- *Things you must do*
Shake the inhaler well immediately before each use. If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of two days, prime the inhaler. Spray the inhaler 4 times 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 Becloten® Inhaler. Tell your doctor immediately if you become pregnant while taking this medication.
Children should use the inhaler under adult supervision, as instructed by the physician.

- *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 Becloten® Inhaler 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. Inhaled steroid treatment should not be stopped abruptly.
Pressurised canister- do not puncture, break or incinerate even when apparently empty.

Side Effects
Like all medicines, Becloten® Inhaler can cause side effects, although not everybody gets them. If you notice any of the

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following serious side effects, stop using this medicine and talk to your doctor straight away. You may need urgent medical treatment.

If immediately after taking a puff of this inhaler, you feel wheezy or tight chested do not take any more puffs. Use your reliever inhaler to help your breathing and contact your doctor immediately. Stop using your inhaler and tell your doctor immediately or go to the Casualty Department at your nearest hospital if the following happens:

a) an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Treatment with *beclometasone* aerosol may affect the normal production of corticosteroids in the body, your doctor may take a blood sample from time to time to check on this.

Keep using your inhaler but see your doctor as soon as possible if you become unwell, particularly with any of the following:

a) abdominal pain
b) weakness
c) vomiting

The following side effects may also occur in patients taking *beclometasone dipropionate.* If you experience any of these effects, keep using your inhaler but see your doctor if they last for a while or they are worrying you:

Very Common

a) candidiasis of the mouth and throat (thrush)- white spots in your mouth and throat.

Common

a) hoarse voice or a sore throat (hoarseness/ throat irritation)

Uncommon

a) rashes, urticaria (raised, itchy rash on the skin), pruritus (itching of the skin), erythema (redness of the skin), bruising (a mark on your skin caused by blood trapped under the surface).

Very Rare

a) oedema (swelling) of the eyes, face, lips and throat.
b) difficulty in breathing (dyspnoea), increase in wheezing, shortness of breath and cough (bronchospasm) anaphylaxis (a serious allergic reaction).
c) Cushing's syndrome (a hormonal disorder).
d) facial puffiness and weight gain (Cushingoid features)
e) adrenal suppression (adrenal glands are unable to produce adequate amounts of cortisol).
f) growth retardation (delayed growth) in children and adolescents.
g) a decrease in bone mineral density (thinning and weakening of the bones).
h) clouding of the lens of the eye (cataract).
i) glaucoma (increased pressure in the eye).

Unknown

a) Psychomotor hyperactivity (a symptom related to a wide range of mood disorders), sleeping problems, depression or feeling worried, restless, nervous, overexcited or irritable behavioural changes (predominantly in children).

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 visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Becloten® Inhaler

Storage

Store below 30ºC. Do not freeze. Protect from direct sunlight. Keep out of reach of children.

The canister should not be broken, punctured or burnt, even when apparently empty.

As with most medications in aerosol canisters, the therapeutic effects of this medication may decrease when the canister is cold.

Disposal

Ask your doctor or pharmacist on how to dispose of used inhaler. Each inhaler contains 200 actuations and patients are advised to keep track on the total number of actuations taken. Always be sure to dispose of used inhaler responsibly, in the recommended way since some of the medicine may remain inside it. The used inhaler should not be disposed of via wastewater or household waste to ensure environmental safety.

Product Description

A pressurised metered-dose inhaler containing not less than 200 actuations clear solution of *beclometasone dipropionate*

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filled in a 19ml aluminium canister fitted with a 50µl plastic and elastomeric metering valve with a white polypropylene actuator and a light brown polypropylene dust cap and packed into individual printed carton. Each actuation delivers 100 microgram *beclometasone dipropionate*.

-Ingredients:
. The active substance is *beclometasone dipropionate* (micronised).

. The other ingredients are *Ethanol* and HFA134a (*1,1,1,2 Tetrafluoroethane*) as excipients.

- *Product Registration Number:*
MAL……

Manufacturer and Product Registration Holder:
Tenang Pharma Sdn Bhd
PT 3337, Jalan Permata 1/2
Arab Malaysian Industrial Park
71800 Nilai, Negeri Sembilan
Darul Khusus, MALAYSIA

Date of Revision:
25th November 2022

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