

BECLATE AQUANASE NASAL SPRAY

Beclomethasone dipropionate (50mcg/spray)

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What BECLATE AQUANASE is used for

Beclate Aquanase is used to prevent and treat the common symptoms of seasonal and perennial (throughout the year) allergic vasomotor rhinitis (inflammation of the mucous membrane inside the nose). Beclate Aquanase can also prevent the small growths inside the nose (nasal polyps) from coming back after they are removed.

How BECLATE AQUANASE works

The active ingredient is beclomethasone dipropionate, a corticosteroid which has an anti-inflammatory and vasoconstrictor (constriction of blood vessels) effect to reduce swelling and irritation in the nose

Before you use BECLATE AQUANASE

-When you must not use it

Do not use Beclate Aquanase:

- if you have untreated fungal, bacterial or viral infections
- if you have tuberculosis (TB) infection in your lungs
- if you have viral infection of eye (ocular herpes simplex)
- if you have unhealed wounds in your nose
- if you have ever had an allergic reaction to beclomethasone dipropionate or any of the other ingredients

-Before you start to use it

Talk to your doctor or pharmacist before using Beclate Aquanase if you have an infection or ulcers in your nose, or you have recently had surgery or an injury to your nose.

Pregnancy and breastfeeding

Talk to your doctor or pharmacist before using Beclate Aquanase if you are pregnant, trying to become pregnant or are breast feeding.

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;

How to use BECLATE AQUANASE

Always shake well before use. Only use in the nose. Do not swallow.

-How much to use

Adults and children over 6 years: Spray 1-2 times into each nostril every morning and evening. Do not use in children below 6 years

When to use it

You should use the spray regularly to get the best results from it.

-How long to use

It takes a few days for this medicine to work hence it is very important that you use it regularly. Do not stop treatment even if you feel better unless told to do so by your doctor.

-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. Taking large amount of this medicine over a short time period may cause suppression of hypothalamic-pituitary-adrenal (HPA) function

While you are using BECLATE AQUANASE

-Things you must do

- Take your medicine exactly as your doctor has told you.

- Tell all the doctors, dentists and pharmacists treating you that you are taking Beclate Aquanase.

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

-Things you must not do

1. Use your Beclate Aquanase as directed by your physician. Do not exceed the recommended dose.

2. This medicine has been specially recommended by your doctor for you. Do not allow any other person to use it.

-Things to be careful of

Change from systemic to topical treatment
The replacement of systemic corticosteroid with Beclate Aquanase can be accompanied by signs of adrenal insufficiency. When transferred to Beclate Aquanase careful attention must be given to individual previously treated for prolonged periods with systemic corticosteroids. This is particularly important in those individual who have associated asthma or other clinical conditions, where too rapid a decrease in systemic corticosteroids may cause a severe exacerbations of symptoms. Although systemic effects have been minimal with recommended doses, this potential increases with excessive doses. Therefore, larger than recommended doses should be avoided.

Side effects

Like all medicines, Beclate Aquanase can have side effects, but not everybody gets them. Stop taking the medicine and seek immediate medical help if you experience:

- Allergic reactions. These may include developing a rash, swelling of the mouth or face or having difficulty breathing.

The side effects are:

- discomfort of the nose such as dryness and irritation
- sneezing
- epistaxis (bleeding from nose)
- impaired wound healing
- unpleasant taste and smell
- nasal septum perforation (hole in the nasal septum the structure that divides the nostrils)
- glaucoma (increased pressure inside the eye)

You may report any side effects or adverse drug reactions directly to the National

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Centre for Adverse Drug Reaction
Monitoring by calling Tel: 03-78835550,
or visiting the website npra.moh.gov.my
(Public --> Reporting Medicinal Problems
/ Side Effects / AEFI/ Vaccine Safety).

Serial Number

NPRA(R4/1)010817/00187

Storage and Disposal of BECLATE AQUANASE

-Storage

Store below 25°C but do not refrigerate.
Keep out of the reach and sight of children.
Do not use this medicine after the 'EXP'
date shown on the pack. Keep the container
in the outer carton to protect from light.

-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

A white homogenous, redispersible
suspension filled in amber glass vials (10
ml) with crimped nasal spray assembly.

Ingredients

-Active Ingredient: each spray contains
Beclomethasone Dipropionate 50
micrograms.

-Inactive ingredients: Avicel RC
(microcrystalline cellulose, sodium
carboxymethylcellulose), dextrose,
polysorbate 80, purified water,
benzalkonium chloride and phenylethyl
alcohol.

-MAL Number: MAL20013987AZ

Manufacturer

Cipla Ltd.
Verna Industrial Estate,
Goa, 403 722
India

Product Registration Holder

Cipla Malaysia Sdn Bhd
Suite 1101, Amcorp Tower,
Amcorp Trade Centre,
18 Persiaran Barat,
46 050 Petaling Jaya,
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Date of revision

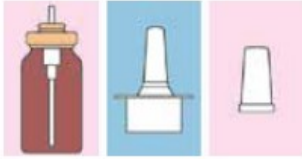
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Instructions for use

Parts of Beclate Aquanase



Bottle with Nozzle Dust Cap
Metered- Dose Atomising
Pump

Before using

1. Shake the bottle gently, then remove the dust cap.
2. Hold the bottle as shown with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.



3. Before using your Beclate Aquanase for the first time, or if you have not used it for a period of time, follow the instructions given below. With the nozzle pointing away from you, press several times as shown until a fine uniform mist comes out of the nozzle.



4. Blow your nose gently.



5. Close one nostril and put the nozzle in the other nostril as shown. Tilt your head slightly forward keeping the nozzle in the upright position.

6. Start to breathe in through your nose and while breathing in press down with your fingers once to release a spray.



7. Breathe out through your mouth. Repeat steps 6 and 7 to inhale a second spray



8. Repeat steps 5, 6 and 7 for the other nostril



After use:

9. Wipe the nozzle with a clean cloth and replace the dust cap.



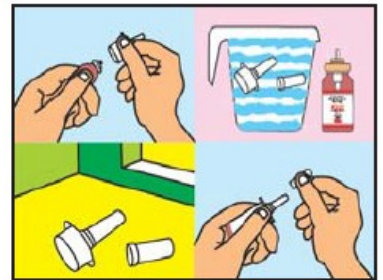
Note:

The first time you use Beclate Aquanase, you may sneeze a few times. This is because the lining of your nose is very sensitive. This is not likely to happen after the first few doses.

Cleansing

Your Beclate Aquanase should be cleaned at least once a week.

To do this:



1. Push the nozzle upwards to detach from the bottle.
2. Wash the nozzle and dust cap in warm water. Shake off excess water and leave to dry in a warm place. Avoid excessive heat.
3. Replace the nozzle and dust cap.
4. If the nozzle becomes blocked remove as above and soak in warm water. Rinse under a cold tap. Allow to dry and refit.

Do not use a pin or other sharp object to unblock the nozzle.