Patient Information Leaflet

BECLATE AQUANASE aqueous nasal spray

SCHEDULING STATUS: S2

BECLATE AQUANASE aqueous nasal spray

Beclomethasone dipropionate

Contains sugar (Glucose)

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do not share BECLATE AQUANASE with any other person.
- Ask your health care provider or pharmacist if you need more information or advise.
- You must see a doctor if your symptoms worsen or do not improve in 14 days.

What is in this leaflet

1. What BECLATE AQUANASE is and what it is used for
2. What you need to know before you use BECLATE AQUANASE
3. How to use BECLATE AQUANASE
4. Possible side effects
5. How to store BECLATE AQUANASE
6. Contents of the pack and other information.

1. What BECLATE AQUANASE is and what it is used for

BECLATE AQUANASE belongs to a group of medicines called corticosteroids. They are also called steroids (cortico-steroids). Steroids are used to reduce inflammation.

BECLATE AQUANASE is used to treat the symptoms of seasonal allergic rhinitis (stuffy nose, runny nose, sneezing and post-nasal drip), including hayfever, by reducing the swelling and irritation in the nose.

2. What you need to know before you use BECLATE AQUANASE

Do not take BECLATE AQUANASE:

- If you are allergic (hypersensitive) to beclomethasone or any of the other ingredients of **BECLATE AQUANASE** (listed in section 6).
- If you have a fungal, viral or bacterial infection.
- If you have tuberculosis, herpex infection of the eyes or unhealed wounds in the nose.
- If you have a history of nose bleeds or bleeding tendencies.
- If you are a child ~~[Children]~~ under the age of six years.
- If you are pregnant or breastfeeding your baby (see **"Pregnancy and breastfeeding**").
- For a period longer than 3 months.

Warnings and precautions

Take special care with BECLATE AQUANASE:

- If you are taking steroids for other conditions.
- If you are taking high doses of other steroids (orally or via injection) with **BECLATE AQUANASE** as it may result in Cushing's syndrome (symptoms

include upper body obesity, rounded face, increased fat around the neck, thinning arms and legs, feeling tired, weakness, high blood pressure, and mood disorders. Children tend to be obese with slowed growth rates.

- If you notice slowed growth rates in children taking BECLATE AQUANASE at the recommended doses. The height of children taking BECLATE AQUANASE for extended period should be regularly monitored.
- If you notice psychological changes or behavioural changes, such as psychomotor hyperactivity (feelings of restlessness along with an increase in motor activity including muscle spasms, shaking and twitching), sleeping disorders, depression, being more aggressive (especially in children), tell your doctor.
- If you have been using **BECLATE AQUANASE** for an extended time, tell your doctor.
- If you have an infection of the nose (or had an operation) or throat, tell your doctor as you may need to discontinue treatment with **BECLATE AQUANASE** or need other medicines for the infection.
- If you have nose bleeds.
- If a patient presents with symptoms such as blurred vision or other visual disturbances tell your doctor.

Other medicines and BECLATE AQUANASE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.

Please tell your doctor if you are taking any of the following medicines as they affect the levels of **BECLATE AQUANASE** in your blood.

- Other steroids, orally or by injection.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

BECLATE AQUANASE contains benzalkonium chloride.

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if the patient has asthma.

How to use BECLATE AQUANASE

Do not share medicines prescribed to you with any other person.

Always use BECLATE AQUANASE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with BECLATE AQUANASE will last. If you have the impression that the effect of BECLATE AQUANASE is too strong or too weak, tell your doctor or pharmacist.

BECLATE AQUANASE is for nasal use only.

Adults and children over 12 years of age:

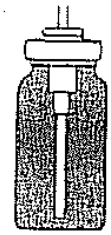
One metered dose (spray) (50 µg) in each nostril, two to four times a day.

or a dosage of two metered doses (sprays) (100 µg) into each nostril twice daily can be used.

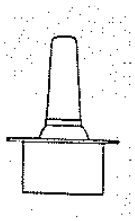
Do not use more than four sprays per nostril per day.

Always tell your doctor and pharmacist if you are taking or plan to take any other prescription or over-the-counter medicines.

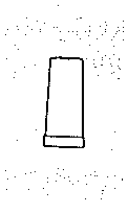
Parts of BECLATE AQUANASE Nasal Spray



Bottle with Metered-Dose Atomising Pump



Nozzle



Dust Cap

Important

1. Use your BECLATE AQUANASE nasal spray as directed by your doctor.

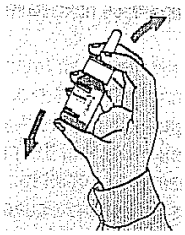
Do not exceed the recommended dose.

2. It takes a few days for BECLATE AQUANASE 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.
3. BECLATE AQUANASE has been specially recommended by your doctor for you. Do not allow any other person to use it.
4. Keep your BECLATE AQUANASE nasal spray out of the reach of children.
5. Protect your BECLATE AQUANASE nasal spray from light. Store at or below 25 °C . but do not refrigerate.

How to use your BECLATE AQUANASE Nasal Spray

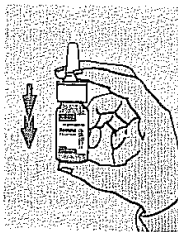
Before using

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 nasal spray 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 your fingers once to release a spray.



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

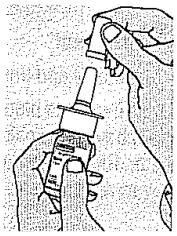


8. Repeat steps 5, 6 and 7 for the other nostril.



After use

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



NOTE

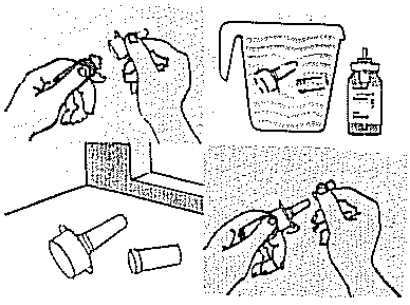
The first time you use BECLATE AQUANASE nasal spray, you may sneeze a few times. This is because the lining of your nose is very sensitive. This is not likely to happen after the first few doses.

BECLATE AQUANASE can, at times cause a few side-effects in certain hypersensitive individuals. If you notice any bleeding from your nose or experience any other discomfort, please inform your doctor.

Cleansing

Your BECLATE AQUANASE Nasal Spray 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 caps.

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.

If you take more BECLATE AQUANASE than you should:

In the event of overdosage (if you spray more doses than you should), or if someone else takes your medicine by mistake, you, or this other person, may experience any of the side effects listed below. In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take BECLATE AQUANASE:

Always take BECLATE AQUANASE as prescribed. If you miss a dose, take the next dose when it is due. Do not take a double dose to make up for the forgotten doses.

4 Possible side effects

BECLATE AQUANASE can have side effects.

Not all side effects reported for BECLATE AQUANASE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BECLATE AQUANASE, please consult your doctor, pharmacist or other healthcare professional for advice**.**

If any of the following happen, stop taking BECLATE AQUANASE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions, which may include a skin rash, fever, difficult breathing,
- wheezing, hives, itching, or swelling of the eyes, face, lips, tongue, throat which may cause difficulty in swallowing or breathing and watery eyes.
- Difficult breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to **BECLATE AQUANASE**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain,
- changes in the way your heart beats, for example, if you notice it beating faster .

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Yeast infections (Candidiasis), nasal irritation or soreness, sneezing, and bleeding from the nose (see “Take special care with BECLATE AQUANASE**”**).
- Sneezing.
- Cough.

Less frequent side effects:

- Adrenal suppression (the adrenal glands don’t produce enough steroid hormones, symptoms may include: chronic worsening fatigue and muscle weakness, loss of appetite, weight loss and abdominal pain. Nausea and vomiting may also occur).
- Aggressive reaction.
- Anxiety.
- Behavioural changes.
- Depression.
- Restlessness.
- Dizziness.
- Headache.
- Lightheadedness.
- Unpleasant taste.
- Unpleasant taste.
- Milder allergic reactions such as redness or skin rashes, and itching.
- Increased pressure in the eye(s), glaucoma or cataract formation.
- Dryness and irritation of the nose and throat, perforation in the nasal septum.
- High blood pressure.
- Rectal bleeding.
- Sore throat.
- Damage to the nose.
- Change in the voice.
- Blocked nose.
- Pneumonia.

- Nausea or vomiting.
- Stomach pain.
- Inflammation (irritation) of your intestines.
- Numbness.
- Inflammation of the bladder.
- Menstrual changes.
- Loss of taste or smell.

Frequency is not known:

- Vision blurred
- Pulmonary eosinophilia (inflammation of the lungs from an increase in eosinophils, a type of white blood cell).
- Suppressed bone formation. Loss of bone marrow density from the hip.
- Slower growth in children.
- Impaired wound healing (wounds healing slower than usual).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse . You can also report side effects to SAHPRA via the the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BECLATE AQUANASE

Side effects may also be reported directly to Cipla Medpro (Pty) Ltd. By an email at: drugsafetysa@cipla.com.

How to store BECLATE AQUANASE

Store all medicines out of the reach of children.

Keep **BECLATE AQUANASE** in a dry place at or below 25 °C

In order to protect from moisture, do not store in bathrooms.

Do not refrigerate.

Do not use **BECLATE AQUANASE** after the expiry date stated on the carton and label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BECLATE AQUANASE contains

The active substance is beclomethasone dipropionate.

Each metered actuation (dose/ spray) contains 50 µg beclomethasone dipropionate.

The other inactive ingredients in **BECLATE AQUANASE** are glucose (anhydrous), microcrystalline cellulose + carboxy methyl cellulose sodium, polysorbate 80 (Tween 80). Benzalkonium chloride and phenyl ethyl alcohol are included as preservatives.

What BECLATE AQUANASE looks like and contents of the pack

BECLATE AQUANASE is a white to off-white homogenous, redispersable suspension.

10 ml amber glass vial fitted with a metering atomising pump and nasal adaptor. Each vial contains 7,5 ml of nasal spray (150 DOSES).

Holder of Certificate of Registration

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R.S.A

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