

BUDENASE AQ NASAL SPRAY 64 MCG /DOSE

Budesonide (64mcg/dose)

What is in this leaflet

1. What BUDENASE AQ NASAL SPRAY 64 MCG /DOSE is used for
2. How BUDENASE AQ NASAL SPRAY 64 MCG /DOSE works
3. Before you use BUDENASE AQ NASAL SPRAY 64 MCG /DOSE
4. How to use BUDENASE AQ NASAL SPRAY 64 MCG /DOSE
5. While you are using BUDENASE AQ NASAL SPRAY 64 MCG /DOSE
6. Side effects
7. Storage and Disposal of BUDENASE AQ NASAL SPRAY 64 MCG /DOSE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What BUDENASE AQ NASAL SPRAY 64 MCG /DOSE is used for

- Seasonal and perennial (throughout the year) rhinitis (inflammation of the mucous lining inside the nose) and non-allergic rhinitis. It is also used to treat small growths inside the nose (nasal polyps).
- It can also prevent nasal polyps from coming back after they are removed.

How BUDENASE AQ NASAL SPRAY 64 MCG/DOSE works

Budenase AQ Nasal Spray 64 mcg/dose contains a medicine called budesonide. This belongs to a group of medicines called corticosteroids. It works by reducing and preventing swelling and inflammation in your nose

Before you use BUDENASE AQ NASAL SPRAY 64 MCG/DOSE

-When you must not use it

You are allergic (hypersensitive) to budesonide or any of the other ingredients of Budenase AQ Nasal Spray 64 mcg /dose. If you are not sure if this applies to you, talk to your doctor or pharmacist before using Budenase AQ Nasal Spray 64 mcg /dose.

Pregnancy and breast-feeding

• If you are pregnant or planning to get pregnant or breastfeeding, talk to your doctor or pharmacist before using Budenase AQ Nasal Spray 64 mcg /dose. Use during pregnancy should be avoided unless there are compelling reasons. Budesonide Nasal Spray can be used

during breastfeeding.

-Before you start to use it

Before you use Budenase AQ Nasal Spray 64 mcg/dose, tell your doctor or pharmacist if:

- You have lung TB (tuberculosis).
- You have fungal or viral infections of the airways

If you are not sure if either of the above apply to you, talk to your doctor or pharmacist before using Budenase AQ Nasal Spray 64 mcg /dose.

-Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Talk to your doctor if:

- You are taking medicines to treat fungal infections (such as itraconazole or ketoconazole).
- You have been taking steroid tablets.

How to use BUDENASE AQ NASAL SPRAY 64 MCG /DOSE

-How much to use

Always use Budenase AQ Nasal Spray 64 mcg /dose exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Read the label to remind you of what they said.

There are insufficient data to recommend the use of Budenase AQ Nasal Spray in children.

Rhinitis

- The usual dose is two sprays of Budenase AQ Nasal Spray 64 mcg /dose into each nostril in the morning. Alternatively, your doctor may ask you to take one spray of Budenase AQ Nasal Spray 64 mcg /dose into each nostril every morning and evening.
- This may be reduced by your doctor once your symptoms have improved.

Nasal polyps

The usual dose is one spray of Budenase AQ Nasal Spray 64 mcg/dose into each nostril every morning and evening.

-When to use it

It is important to use Budenase AQ Nasal Spray 64 mcg /dose regularly. Try to use it before you encounter whatever causes the allergy. For example, pollen is what causes hay fever, so you will be more at risk outdoors.

-How long to use it

Treatment for allergies such as hay fever and for nasal polyps can continue for up to 3 months. You may not notice any effects of the medicine for the first few days. Do not stop taking it. Keep taking the medicine as you have been told to. If you still feel no different after a few more days, talk to your doctor.

-If you forget to use it

If you forget to take a dose, take it as soon as you remember. However, if it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten 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 use only as much as your doctor recommends; using more make your symptoms worse. If you take too many doses of Budenase AQ Nasal Spray 64 mcg/dose, talk to your doctor or pharmacist straight away. Inhalation of high doses of corticosteroids may lead to suppression of the hypothalamic-pituitary-adrenal (HPA) axis function

While you are using it

-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 Budenase AQ Nasal Spray 64mcg/dose. Tell your doctor immediately if you become pregnant while taking this medication

-Things you must not do

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

- **Long-term treatment:** If you use Budenase AQ Nasal Spray 64 mcg/dose

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every day for a long time, your doctor will need to have a regular check of the inside of your nose (the nasal mucosa) every 6 months.

- Children and adolescents: If a child or adolescent is prescribed Budenase AQ Nasal Spray 64 mcg/dose and uses a high dose for a long time, the doctor will need to check how well they are growing.
- Concomitant treatment may sometimes be necessary to counteract eye symptoms caused by the allergy
- If higher than recommended doses is being used, additional systemic corticosteroid should be considered during periods of stress or elective surgery.

Side effects

Like all medicines, Budenase AQ Nasal Spray 64 mcg /dose can cause side effects, although not everybody gets them. If any of the following happen to you, stop using Budenase AQ Nasal Spray 64 mcg /dose and talk to your doctor straight away:

Skin rash, itching, nettle rash (hives), blistering of the skin. Swelling of your face, lips, tongue or throat (this may make it difficult to swallow). These are uncommon. If any of the above occurs, you may be having an allergic reaction.

Other possible side effects

Common:

- Sneezing, dry nose, or stinging in your nose. These can happen straight after using Budenase AQ Nasal Spray 64 mcg /dose.
- Bleeding from the nose.

Rare:

- Glaucoma (increased pressure in the eye).

Very rare:

- Ulceration on the inside of the nose.
- Perforation of the membrane separating the nostrils (the nasal septum).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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 npra.moh.gov.my (Public --> Reporting Medicinal Problems / Side Effects / AEFI/ Vaccine Safety).

Storage and Disposal of BUDENASE AQ NASAL SPRAY 64 MCG /DOSE

-Storage

- Store below 25°C.
- Keep out of the reach and sight of children.
- Do not use Budenase AQ Nasal Spray 64 mcg /dose after the expiry date stated on the packaging.

-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, off white homogenous redispersible suspension filled in 10 ml amber glass vial with crimped nasal spray assembly

Ingredients

-Active ingredient: Budesonide. Budenase AQ Nasal Spray 64 mcg /dose contains 64 micrograms of budesonide in each spray.

-Inactive ingredients: Disodium edetate, potassium sorbate, glucose (anhydrous), microcrystalline cellulose, carboxy methylcellulose sodium, polysorbate 80, hydrochloric acid and water for injection.

MAL Number: MAL11030012AZ

Manufacturer

Cipla Ltd.

L-139 to L-146

Verna Industrial Estate, Verna Goa, India

Product Registration Holder

Cipla Malaysia Sdn Bhd

Suite 1101, Amcorp Tower,

Amcorp Trade Centre,

18 Persiaran Barat,

46 050 Petaling Jaya,

Selangor, Malaysia.

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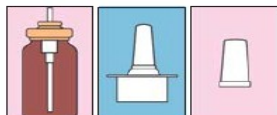
BUDENASE AQ NASAL SPRAY 64 MCG /DOSE

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How to use BUDENASE AQ NASAL SPRAY 64 MCG /DOSE

Instructions for use

Parts of Budenase AQ Nasal Spray 64 mcg /dose



Bottle with Metered-Dose Atomising Pump Nozzle Dust Cap

Important

1. Keep your Budenase AQ Nasal Spray 64 mcg /dose out of the reach of children. Protect your Budenase AQ Nasal Spray 64 mcg /dose from light and below 25°.

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 Budenase AQ Nasal Spray 64 mcg /dose for the first time, or if you have not used it for a longer period, follow the instructions given below.

4. With the nozzle pointing away from you, press several times as shown until a fine uniform mist comes out of the nozzle



5. Blow your nose gently.



6. 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.

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



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



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



After use:

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



Note:

1. The first time you use 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.
2. This medication 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 Budenase AQ Nasal Spray 64 mcg /dose should be cleaned atleast 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.