

BUDENASE AQ NASAL SPRAY 100MCG/DOSE

Budesonide (100mcg/dose)

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What BUDENASE AQ is used for

BUDENASE AQ is used to treat and prevent the effects of seasonal and perennial (throughout the year) allergies (such as hayfever) which can cause inflammation inside the nose (rhinitis).

-It is also used to treat non-allergic rhinitis and small growths inside the nose (nasal polyps).

-It can also prevent the nasal polyps from coming back after they are removed.

How BUDENASE AQ works

BUDENASE AQ 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

-When you must not use it

Do not use BUDENASE AQ if:

- You are allergic (hypersensitive) to budesonide or any of the other ingredients of BUDENASE AQ
- you have untreated fungal, bacterial or viral infections
- you have viral infection of eye (ocular herpes simplex)
- you have tuberculosis (TB) infection in your lungs
- you have unhealed nasal wounds.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, trying to get pregnant or think you may be pregnant or if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine. BUDENASE AQ should only be used in pregnancy if your doctor feels the benefit of using the spray outweighs any risks.

-Before you start to use it

Talk to your doctor or pharmacist before using BUDENASE AQ. You should tell your doctor before taking any of the following medicines:

- if you have fungal or viral infection.

If you use BUDENASE AQ long-term your doctor will check the lining of your nose every 6 months to check that it is in good condition.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including the following:

- medicine to treat a fungal infection (e.g. ketoconazole)
- you are taking antibiotics (such as erythromycin)
- you are taking medicines to treat depression such as (fluoxetine)
- you are taking medicines to treat HIV infection such as (ritonavir)
- you are taking medicines to relieve pain or fever such as (aspirin)
- you are taking medicine for abortion such as (mifepristone)
- you are taking steroids tablet/syrup

Vaccines can be taken as recommended in healthy persons.

How to use BUDENASE AQ

-How much to use it

Always use BUDENASE AQ exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Rhinitis

• Adults and children over 6 years: Two sprays into each nostril every morning. In some cases, your doctor may advise one spray into each nostril every morning and evening.

• Maintenance dose: Use the lowest effective dose (1 spray in each nostril once daily)

• Your doctor may reduce this dose once your symptoms improve.

You will need to use the Budesonide spray regularly.

Nasal polyps

The usual dose is one spray of BUDENASE AQ into each nostril every morning and evening.

BUDENASE AQ is not recommended for

use in children below 6 years

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use

- Speak to your doctor first before stopping this medicine.

- Treatment for nasal polyps can continue for up to 3 months.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-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 label or as advised by your doctor. You should use only as much as your doctor recommends; using more may make your symptoms worse. If you accidentally take too much of your medicine tell your doctor. Using too much may cause signs and symptoms of hypercorticism (high level of hormones), suppression of hypothalamic-pituitary-adrenal (HPA) function and suppression of growth in children

While you are using it

-Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking BUDENASE AQ.
- Tell your doctor immediately if you become pregnant while taking this medication

-Things you must not do

1. 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.

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

-Long term use of budesonide may cause suppression of growth in children. Closely monitor the growth of children.

-During long-term high-dose therapy,

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monitoring of blood and adrenal function is advisable.

Side effects

Possible side effects

Like all medicines, BUDENASE AQ can cause side effects, although not everybody gets them.

If any of the following allergic reaction happen to you, stop using BUDENASE AQ and tell your doctor immediately:

- Skin rash, itching, lumpy rash (hives), blistering of the skin. Swelling of your face, lips, tongue or throat (this may make it difficult to swallow).

Other possible side effects:

- Discomfort in your nose or stinging in your nose. These can happen straight after using BUDENASE AQ.
- Bleeding from the nose.
- Throat irritation, increased cough.
- Extremely rare, ulceration on the inside of the nose and perforation of the membrane separating the nostrils (the nasal septum) may occur.

If any side effect gets 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

-Storage

Store below 25°C Protect from light. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

-What it looks like

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

-Ingredients

- Active ingredient: Budesonide
- Inactive ingredients: Anhydrous glucose, Avicel RC, polysorbate 80, potassium sorbate, disodium edetate, hydrochloric acid and water for injection.

-MAL Number: MAL 20031746AZ

Manufacturer

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Product Registration Holder

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