

# **APOHEALTH Budesonide Hayfever**

Contains the active ingredient budesonide

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## **Consumer Medicine Information**

**For a copy of a large print leaflet, Ph: 1800 195 055**

## **What is in this leaflet**

**Read this leaflet carefully before taking your medicine.**

This leaflet answers some common questions about APOHEALTH Budesonide Hayfever. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

### **Ask your doctor or pharmacist:**

- if there is anything you do not understand in this leaflet,

- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

## **What this medicine is used for**

The name of your medicine is APOHEALTH Budesonide Hayfever. It contains the active ingredient Budesonide.

It is used for the prevention or treatment of seasonal allergic rhinitis (eg due to pollen) for up to six months in adults and children 12 years of age and over and perennial (non-seasonal) allergic rhinitis (eg due to cats, dust mites) in adults 18 years and over.

Symptoms of Allergic Rhinitis can include:

- stuffiness (congestion) in the nose
- discharge, itching and sneezing

This medicine is available only from a pharmacy.

## **How it works**

Budesonide belongs to a family of medicines called corticosteroids.

These medicines work by helping to reduce inflammation.

There is no evidence that this medicine is addictive.

It may take a few days of use before you feel the full effects of the medicine. In rare cases it may take up to 2 weeks

If you suffer moderate to severe symptoms, you may wish to start treatment before the beginning of the 'pollen' season.

## **Use in children**

**Do not use in children under 12 years of age.**

**Do not use in children under 18 years of age for non-seasonal hayfever**

## **Before you use this medicine**

### **When you must not use it**

**Do not use this medicine if:**

- **You have or have had any of the following:**
  - **a tendency to bleed or recurrent nose bleeding**
  - **a severe nose infection, especially fungal infection.**

- **You are hypersensitive to, or have had an allergic reaction to, budesonide or any of the ingredients listed at the end of this leaflet.**
- **Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.**

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

**Do not continue using this medicine if you have already used it, or a similar corticosteroid nasal spray, for 6 months or longer.**

**Do not use if the expiry date (EXP) printed on the pack has passed.**

**Do not use if the packaging is torn, shows signs of tampering or it does not look quite right.**

## **Before you start to take it**

**Before you start taking this medicine, tell your pharmacist or doctor if:**

1. You have allergies to:
  - any other medicines

- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
    - tuberculosis
    - infection of the nose, sinus, mouth, throat, lungs or eye
    - sores in the nose, including open sores
    - recent injury or surgery to your nose.

Tell your pharmacist or doctor if you are taking other corticosteroid medicines, either by mouth, as eye drops, as an asthma inhaler or by injection.

3. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breastfeed.

Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

5. You are currently receiving or are planning to receive dental treatment.

6. You are planning to have surgery or an anaesthetic.

7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

## **How to use this medicine**

Follow carefully all the directions provided to you on the product packaging, the package insert and in this information leaflet. If you do not understand the instructions, ask your pharmacist or doctor for help.

Administration to children 12 years and over should be aided by an adult to ensure correct use.

## **How much to use**

### **Adults and Children 12 years and over (adults 18 years and over for non-seasonal hayfever):**

The initial dose is four sprays into each nostril once a day or two sprays into each nostril twice a day. Once your symptoms have improved, you may be able to lower the dose to as little as one spray into each nostril once a day. If symptoms get worse again, the dosage may be increased back to four sprays into each nostril once a day.

**Always use the lowest dose which controls your symptoms.**

**Do not use in children under 12 years of age.**

## **When to use it**

It may take a few days to significantly improve symptoms, therefore, to prevent the onset of symptoms, start to use APOHEALTH Budesonide Hayfever a few days before expected exposure to one of your usual 'triggers'.

If you suffer moderate to severe symptoms, you may wish to start treatment before the beginning of the 'pollen' season.

It is very important that you use APOHEALTH Budesonide Hayfever regularly. If you stop the treatment when you feel better, your symptoms may return as the medication wears off.

## **How long to use it**

If you have used the spray for 7 days and the symptoms have not improved, or not improved enough, see your pharmacist or doctor for advice.

Do not use a larger dose or use your nasal spray more often than recommended. Do not use more than 4 sprays in each nostril daily.

**If symptoms worsen during treatment, see your pharmacist or doctor immediately.**

**Do not use for more than 6 months continuously without the advice of a doctor. If you have already used a similar nasal spray for 6 months, or are currently using a similar nasal spray, seek the advice of your pharmacist or doctor before using this medicine.**

**This medicine must be discarded 60 days after you first open it.**

If you have the 120 spray pack, depending on the dose you use, you may have some left over medicine.

**The medicine must be discarded 60 days after opening, regardless of whether there are sprays remaining.**

## **About your nasal spray**

Your nasal spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray and to replace it after use. Do not pierce the nasal applicator.

If you are using the spray for the first time, prime the pump by pumping the spray 8 times until a fine mist is produced. If you have not used the pump for 14 days or more reprime by pumping 2 or more times until a fine spray appears.

It is important to clean the nozzle regularly; otherwise, it may not work properly. Remove the dust cap and gently pull off the nozzle. Wash the nozzle and dust cap in warm water and then rinse under a running tap. Allow the nozzle to dry. Push the nozzle back onto the bottle and replace the dust cap. The pump will need to be reprimed when first used after cleaning.

## **How to use it**

1. Gently blow your nose to clear your nostrils, if necessary.

2. Shake the bottle gently for a few seconds and remove the protective cap.
3. Hold the bottle firmly with your index and middle finger on either side of the spray tip and your thumb underneath the bottle
4. Insert the spray tip into your nostril (the tip should not reach far into your nose). Close the other nostril with a finger and lean your head slightly forward so the spray will aim toward the back of your nose.
5. For each spray, activate the pump by quickly and firmly pressing down on the white collar while holding the base of the bottle with your thumb. Breathe gently inward through the nostril.
6. After spraying into your nostril, lean your head backward for a few seconds.
7. If a second spray is needed in the same nostril, repeat steps 3 through 6.
8. Repeat steps 3 through 7 for your other nostril.
9. Avoid blowing your nose for 15 minutes after you use budesonide nasal spray.
10. Wipe the spray tip with a clean tissue, and replace the protective cap. Store the bottle in an upright position.

## **If you forget to take it**

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for missed doses.**

If you are not sure what to do, ask your doctor or pharmacist.

## **If you take too much (overdose)**

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

## **While you are using this medicine**

### **Things you must do**

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests

- you are going to have surgery or an anaesthetic or are going into hospital.
- Go to your doctor immediately if you notice symptoms of a bacterial infection. These symptoms may include fever, persistent face/tooth pain on one side of the face, swelling around the eye area, or worsening of symptoms after an initial improvement.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

## **Things you must not do**

### **Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Take your medicine for a longer than 6 months continuously without the advice of a doctor.
- Stop taking your medicine suddenly, or change the dosage, unless advised to do so by your doctor.
- Take this medicine if you are already taking a similar nasal spray, or have used a similar nasal spray

continuously over the last 6 months without the advice of a pharmacist or doctor.

## **Things to be careful of**

This medicine generally does not cause any problems with your ability to drive a car or operate machinery.

**If you have a lower resistance to infection, avoid coming into contact with anyone who has measles or chickenpox, especially while you are using cortisone-type medicines. Tell your doctor if you do.**

## **Possible side effects**

Tell your doctor as soon as possible if you do not feel well while you are taking budesonide or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor if you notice any of the following:**

- headache
- nausea
- sneezing
- nasal irritation

- nosebleeds
- nasal crust
- dry mouth or nose
- sore throat
- cough
- disturbances of taste or smell
- diarrhoea
- abdominal pain.

There is evidence that corticosteroid nasal sprays may reduce the speed of growth in children. The growth of children receiving corticosteroid nasal sprays should be monitored routinely.

If you have eye pain or visual disturbances, stop treatment and see your doctor.

Other side effects not listed above may occur in some patients.

## **Allergic reactions**

**If you think you are having an allergic reaction to budesonide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

## **Storage and Disposal**

### **Storage**

Keep your nasal spray upright in a cool dry place where the temperature will stay below 25°C. Do not freeze.

After opening, please discard product after 60 days.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Disposal**

If your doctor or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

## **Product description**

### **What APOHEALTH Budesonide Hayfever looks like**

APOHEALTH Budesonide Hayfever is a white suspension contained in an amber glass bottle with a metered-dose, manual spray pump for intranasal administration.

## **Ingredients**

Each actuated spray contains 32 µg of the active ingredient budesonide.

It also contains the following inactive ingredients:

- potassium sorbate
- glucose
- disodium edetate,
- microcrystalline cellulose
- sodium carboxymethyl cellulose
- polysorbate 80

- hydrochloric acid
- purified water

This medicine is gluten-free, lactose-free, tartrazine-free and free of other azo dyes.

APOHEALTH Budesonide Hayfever is available in bottles of 120 sprays.

## **Australian Registration Numbers**

APOHEALTH Budesonide Hayfever: AUST R 259935

## **Sponsor**

Apotex Pty Ltd

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