

# STEROCLEAR® HAYFEVER

Active ingredient(s): *Budesonide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SteroClear® Hayfever. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SteroClear® Hayfever.**

Where to find information in this leaflet:

1. [Why am I using SteroClear® Hayfever?](#)
2. [What should I know before I use SteroClear® Hayfever?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use SteroClear® Hayfever?](#)
5. [What should I know while using SteroClear® Hayfever?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using SteroClear® Hayfever?

**SteroClear® Hayfever contains the active ingredient budesonide, 32 micrograms per spray.** This belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation

**SteroClear® Hayfever is sprayed into the nose to help prevent and treat allergic rhinitis (hayfever).** Hayfever is an inflammation or swelling of the nose lining (which may cause blockage, runny nose, itching and/or sneezing). This is often, but not always, due to an allergy to something in the air (e.g. pollen, dust mites). Seasonal allergic rhinitis is an allergic condition generally triggered by pollens (e.g. grass, weeds, and sometimes trees) in the air and is most common during the Spring and Summer months. Perennial allergic rhinitis is an allergic condition that may be triggered by dust mites, animals (particularly cats) or mould spores and can occur throughout the year.

**SteroClear® Hayfever is not addictive.**

## 2. What should I know before I use SteroClear® Hayfever?

### Warnings

**Do not use SteroClear® Hayfever if:**

- **You are allergic to** any medicines containing budesonide or any other corticosteroid medicines, such as some asthma medicines, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- **You have frequent nose bleeds:** Your condition may cause nose bleeds and still require treatment. Discuss with your doctor if you have any concerns
- **You have severe nasal infections especially candidiasis (thrush)**

**Do not give SteroClear® Hayfever to a child under the age of 12 years.** SteroClear Hayfever is not recommended for use in children under 12 years of age.

**Do not use SteroClear® Hayfever after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using SteroClear® Hayfever, talk to your pharmacist or doctor.

**Check with your doctor or pharmacist if you:**

- are allergic to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - nasal, sinus or chest infection
  - recent injury or surgery to your nose
  - open sores in your nose
  - severe nasal congestion or obstruction
  - tuberculosis (TB) or have been exposed to someone who has tuberculosis, chicken pox or measles
  - glaucoma
  - cataracts or have eye infection
  - diabetes

If you have not told your pharmacist or doctor about any of the above, tell them before you start using SteroClear® Hayfever.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines and SteroClear® Hayfever may interfere with each other. These include:**

- other corticosteroid medicines for conditions such as asthma, allergies or skin rash. These may include tablets, asthma inhalers, nasal sprays, or eye/nose drops.
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole)
- cimetidine, a medicine used to treat reflux and stomach ulcers
- some antibiotic medicines (including erythromycin, clarithromycin).

These medicines may be affected by SteroClear Hayfever®, or may affect how well it works. You may need different amounts of SteroClear® Hayfever, or you may need to use a different medicine. Your pharmacist or doctor will advise you.

Your pharmacist and doctor have more information on medicines to be careful with or avoid while using SteroClear® Hayfever.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SteroClear® Hayfever.**

### 4. How do I use SteroClear® Hayfever?

**To prevent symptoms, start using SteroClear® Hayfever:**

- before the hayfever season; or
- before coming into contact with something you know will cause your hayfever

If you start using SteroClear® Hayfever early, it will help reduce the severity of your symptoms.

**SteroClear® Hayfever can only be used in:**

- Adults and children 12 years and over for the treatment and prevention of seasonal allergic rhinitis, and
- Adults (18 years and over) for the treatment and prevention of perennial allergic rhinitis.

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

#### How much to use

**When you first start using SteroClear® Hayfever, the usual starting dose is:**

- FOUR sprays into EACH nostril in the morning; or
- TWO sprays into EACH nostril twice a day (in the morning and evening).

**Do not use more than eight sprays each day.** It may take a few days of using SteroClear Hayfever before you notice any improvement in your symptoms. See your pharmacist or doctor if your symptoms are not relieved within 7 days.

**Once your symptoms improve:** After your hayfever has improved, you should gradually reduce the number of sprays you put into each nostril to the lowest number that controls your symptoms. This may be ONE spray into EACH nostril in the morning.

#### How long to use SteroClear® Hayfever

SteroClear® Hayfever should be used regularly to keep your symptoms under control. Your pharmacist or doctor will tell you how long to use SteroClear Hayfever for.

Do not use for more than 6 months without the advice of your pharmacist or doctor.

#### Prevention of seasonal allergic rhinitis symptoms:

To help prevent symptoms you should start your treatment before your symptoms are likely to occur (e.g. early Spring)

#### How to use SteroClear® Hayfever

If you do not understand the instructions, ask your pharmacist or doctor for help.

Gently blow your nose before using SteroClear Hayfever.

Use only in your nose.

#### Instructions for use

1. Shake the bottle well before use. Remove the dust cap from the nasal applicator.



2. Hold the nasal spray as shown. Prime the pump by firmly pressing downwards on the white collar. Pump several sprays (5-10) into the air until you get a consistent fine mist. Repeat until a fine spray is produced. The nasal spray is now ready for use. It will not require repriming unless infrequently used or disassembled. If you do not use SteroClear® Hayfever every day, you will need to pump one spray into the air before you use it.



3. Gently blow your nose to clear the nostrils. Tilt your head forward slightly, close one nostril and carefully insert the nasal applicator into the other nostril.



4. Holding the bottle upright, press firmly downwards once or twice on the white collar to deliver the number of sprays required. Breathe gently inwards through the nostril.



5. Then breathe out through your mouth.
6. Repeat the procedure in the other nostril.
7. Replace the dust cap.

#### **Cleaning Instructions**

1. Clean the upper plastic parts regularly.
2. Remove the protective cap and lift off the white nasal applicator.
3. Wash the plastic parts in warm water and allow to dry completely before replacing them.
4. After cleaning, pump two sprays into the air before you use it.

#### **If you forget to use SteroClear® Hayfever**

If you miss a dose of SteroClear® Hayfever, use it as soon as you remember.

Do not use a double dose to make up for the dose that you missed.

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

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

#### **If you use too much SteroClear® Hayfever**

If you think that you have used too much SteroClear® Hayfever, you may need urgent medical attention.

##### **You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using SteroClear® Hayfever?**

### **Things you should do**

- Follow all instructions given to you by your pharmacist or doctor.
- Ask your pharmacist or doctor to examine your nose from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using SteroClear® Hayfever.

Tell any other doctors, dentists or pharmacists that you visit that you are using SteroClear® Hayfever.

### **Things you should not do**

- Do not use SteroClear® Hayfever to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not give SteroClear® Hayfever to anyone else, even if they have the same condition as you.

### **Looking after your medicine**

#### **Cleaning your applicator**

Remove the dust cap, press gently upwards on the white collar and the nasal applicator will come free.

Wash the applicator and dust cap under lukewarm water. Dry and replace.

If the nasal applicator becomes blocked, remove the dust cap, unscrew the pump mechanism from the bottle and soak it in warm water for a few minutes. Rinse under lukewarm water, dry and reassemble on the bottle.

Do not attempt to unblock the applicator with a pin or other sharp object.

#### **Storage**

Keep SteroClear® Hayfever in a cool dry place where the temperature stays below 30 °C. Do not freeze.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### **When to discard your medicine (as relevant)**

Discard 60 days after first opening.

### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

**Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using SteroClear® Hayfever.**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Do not be alarmed by the following list of side effects. You may not experience any of them.

### [Less serious/common] side effects

| Less serious side effects  | What to do   |
|--|--|
| <b>Nose - related:</b> <ul style="list-style-type: none"><li>• Sneezing after spraying or irritated nose</li><li>• Nose bleeding</li><li>• Nasal crust</li><li>• Dry nose</li><li>• Sinusitis</li></ul> <b>Throat/ mouth - related:</b> <ul style="list-style-type: none"><li>• Itching or sore throat</li><li>• Dry mouth</li><li>• Cough or difficulty breathing</li><li>• Increased amount of sputum</li></ul> <b>Body as a whole:</b> <ul style="list-style-type: none"><li>• Headache</li><li>• Dizziness</li><li>• Tiredness</li></ul> | <b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b><br><br>These are more common side effects of your medicine. They are usually mild and only last for a short time. |

### [Serious/rare] side effects

| Serious side effects   | What to do  |
|--|---|
| <b>Swelling/ allergy - related:</b> <ul style="list-style-type: none"><li>• Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li><li>• Severe rash</li><li>• A skin rash, wheezing or breathlessness – these may be symptoms of an allergic reaction</li></ul> <b>Nose/ sinus - related:</b> <ul style="list-style-type: none"><li>• An ulcer (open wound) in your nose</li><li>• Sign or symptoms of a nasal or sinus infection such as a persistent fever, pain or swelling, or discoloured nasal discharges.</li><li>• Nose bleeds</li></ul> | <b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b><br><br>These may be serious side effects. You may need urgent medical attention. Serious side |

|  |                   |
|--|-------------------|
| <b>Eye/ vision - related:</b> <ul style="list-style-type: none"><li>• Change in vision</li><li>• Eye pain or visual disturbances</li></ul> | effects are rare. |
|--|-------------------|

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Corticosteroids taken through the nose for long periods may affect how children grow. In rare cases, some children may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a child's height.

Ask your pharmacist or doctor to answer any questions you may have.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What SteroClear® Hayfever contains

|   |  |
|---|--|
| <b>Active ingredient (main ingredient)</b>      | Budesonide   |
| <b>Other ingredients (inactive ingredients)</b> | Dispersible cellulose<br>Anhydrous glucose<br>Polysorbate 80<br>Potassium sorbate<br>Disodium edetate<br>Hydrochloric acid<br>Purified water |
| <b>Potential allergens</b>                      | Nil  |

**Do not take this medicine if you are allergic to any of these ingredients.**

### What SteroClear® Hayfever looks like

SteroClear® Hayfever comes in a brown glass bottle containing approximately 120 doses, with a metered-dose pump (Aust R 374350).

## **Who distributes SteroClear® Hayfever**

AFT Pharmaceuticals Pty Ltd.

North Ryde, NSW 2113

Email: [customer.service@aftp pharm.com](mailto:customer.service@aftp pharm.com)

This leaflet was prepared in November 2022.