**Budesonide aerosol solution 200 micrograms/dose**

**What is budesonide allgen 200 cfk-free aerosol and what is it used for?**This medicine is an aerosol solution containing an active ingredient that you inhale directly into your lungs through your mouth. The active ingredient, budesonide, belongs to a group of medicines called corticosteroids. These are also known as steroids and have an anti-inflammatory effect that reduces swelling and irritation in the airways.

* This medicine is a preventive treatment for symptoms: it treats inflammation and is used to prevent asthma symptoms.
* An ongoing asthma attack will not be interrupted. Therefore, you should always have a fast-acting bronchodilator with you.
* This medicine can be used to treat mild, moderate, and severe forms of persistent bronchial asthma.

**When should you not use this medicine or use it with extra caution?  
When should you not use this medicine?**

* You are allergic to any of the ingredients in this medicine.
* Consult your doctor for advice.

**When should you use this medicine with extra caution?**

**Contact your doctor or pharmacist before using this medicine if:**

* You suffer from severe liver disease.
* You have ulcers in the gastrointestinal tract (gastrointestinal ulcers).
* You are being treated or have ever been treated for tuberculosis (TB) or other respiratory tract infections.
* You are pregnant, planning to become pregnant, or breastfeeding.
* If you experience oral candidiasis (a certain fungal infection of the mouth) during the treatment, inform your doctor. You may need antifungal treatment or even need to stop the treatment.

**How to use this medicine?**In the case of paradoxical bronchospasm (opposite effect of bronchoconstriction) with an acute increase in wheezing after inhalation, discontinue the treatment immediately.

Contact your doctor if you experience blurred vision or other visual disorders.

**Children and adolescents up to 18 years:** Regularly monitor the height growth of children undergoing prolonged treatment and inform your doctor.

**Are you using other medicines?**Inform your doctor or pharmacist if you are using or have recently used any other medicines, or if there is a possibility that you will use other medicines in the near future. This includes medicines that do not require a prescription.

It is particularly important to inform your doctor when using the following medicines:

* Medicines containing corticosteroids.
* Antifungal agents such as ketoconazole or itraconazole.
* Medicines containing disulfiram or metronidazole (see "Budesonide aerosol, aerosol solution 200 micrograms/dose contains small amounts of glycerol and ethanol").
* HIV protease inhibitors or other strong CYP3A4 inhibitors.
* Estrogens and contraceptive steroids (contraceptives).
* Some medicines can enhance the effects of Budesonide aerosol, and your doctor may want to monitor you carefully if you are using these medicines (including some HIV medicines: ritonavir, cobicistat).

When using any of the above medicines, your doctor may prescribe other medicines or adjust the dose of Budesonide, aerosol solution 200 micrograms/dose, or the other medicine.

If you are undergoing an ACTH stimulation test to detect inadequate pituitary function (hypopituitarism), it may give false results (low values).

Your doctor may have prescribed other medicines for your respiratory problems. It is essential to continue using these products regularly. DO NOT STOP taking these products or change the dosage when you start using this medicine.

**Pregnancy and breastfeeding:** If you are pregnant, planning to become pregnant, or breastfeeding, consult your doctor before using this medicine. Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Then contact your doctor or pharmacist before using this medicine. If you become pregnant while using this medicine, contact your doctor immediately. Worldwide experience with inhaled budesonide has not shown an increased risk of adverse effects for the fetus and the newborn during pregnancy. Budesonide can be used during breastfeeding.

**Driving and using machinery:** This medicine does not affect driving ability and the ability to use machinery.

Budesonide, aerosol solution 200 micrograms/dose contains glycerol and ethanol. This medicine contains 8.4 mg alcohol (ethanol) per inhalation, equivalent to 0.12 mg/kg in adults and 0.42 mg/kg in children. The amount per inhalation in this medicine is equivalent to less than 1 ml of beer or wine. There is a small amount of alcohol in this medicine, which is so little that you will not notice it. Ethanol can cause problems in very sensitive patients being treated with a medicine containing disulfiram or metronidazole. This medicine contains glycerol, which may cause headaches, stomach upset, and diarrhea.

**How to use this medicine?**

This medicine is for inhalation.

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor.

Your doctor will regularly check to ensure that you are using the optimal dose of this medicine. Your treatment will be adjusted to the lowest dose (maintenance dose) that keeps your symptoms under control. NEVER change the dosage on your own without first consulting your doctor.

It is important to continue using this medicine for the entire period prescribed by your doctor. It takes a few days for this medicine to start working, so it is important to use it regularly.

**Adults and adolescents:** The usual dosage is 200 micrograms (1 inhalation) 2-4 times a day. The maintenance dose is typically 200 micrograms (1 inhalation) per day. The maximum daily dosage is 1600 micrograms.

**Use in children:** Children aged 6 to 12 years:

The usual dosage is 200 micrograms (1 inhalation) daily. The maximum dosage is 400 micrograms.

If your child is using this medicine, make sure they know how to use the device correctly. Inhalation in children should be supervised by an adult. It may be helpful to pinch your child's nostrils closed during inhalation.

**Use of corticosteroids:** When you start using this medicine as a replacement for corticosteroid tablets or when you use higher doses of inhaled corticosteroids for a prolonged period, you may need additional steroids in a stress situation. Stressful situations can occur during hospitalization after an accident, severe injury, or before surgery. In such cases, your treating doctor will decide whether it is necessary to increase your corticosteroid dose and may prescribe some steroid tablets or a steroid injection.

**Instructions for use:** See "Instructions for the use of Budesonide, aerosol solution 200 micrograms/dose" at the end of this leaflet. It is recommended to rinse your mouth with water and then spit out the water after each use of the aerosol to reduce the risk of possible Candida infection.

**Have you used too much of this medicine?**It is important to use the dose as indicated on the pharmacy label or as advised by your doctor. Do not increase or decrease the dose without discussing it with your doctor. If you have used too many doses of this medicine, contact your doctor or pharmacist as soon as possible.

**Did you forget to use this medicine?**If you forgot to use a dose, just use the next dose at the usual time. Do not take a double dose to make up for a missed dose.

**If you stop using this medicine:** Do not stop the treatment, even if you feel better, unless instructed by your doctor. Suddenly stopping this medication can worsen your asthma.

**If your asthma worsens:** If your symptoms worsen or are difficult to control (e.g., when you use your quick-relief bronchodilator more frequently) or if the quick-relief bronchodilator does not improve your symptoms, contact your doctor immediately. Your asthma may worsen, and your doctor may need to adjust your dose of this medicine or prescribe an alternative treatment.

When switching from corticosteroid tablets to inhalation therapy, you may not feel as well, even when your breathing improves. In this case, contact your doctor, but DO NOT STOP the treatment unless instructed to do so.

Do you have any other questions about the use of this medicine? Contact your doctor or pharmacist.

**Possible Side Effects**Like all medicines, this medicine can cause side effects, although not everyone gets them.  
If a side effect occurs, it is likely to be mild and temporary. However, some side effects may require medical attention.

Side effects can be severe and may require medical assistance.

**Possible side effects include: Common (affects less than 1 in 10 people):** Voice changes (hoarseness), cough, throat irritation, fungal infection in the mouth (oropharyngeal candidiasis), difficulty swallowing.

**Uncommon (affects less than 1 in 100 people):** Anxiety, depression, trembling, cataracts, blurred vision, and muscle spasms.

**Rare (affects less than 1 in 1,000 people):** Bruising, skin thinning, skin rash, rash with severe itching and the formation of hives (urticaria), skin inflammation (dermatitis), itching (pruritus), skin redness (erythema), allergic reaction (anaphylactic reaction), sudden fluid accumulation in the skin and mucous membranes (e.g., throat or tongue), breathing difficulties, and/or itching and skin rash, often as an allergic reaction (angioedema), decreased or increased cortisol levels in the blood (hypercorticism or hypocorticism), bronchospasm (constriction of the airway muscles causing difficulty breathing).

Restlessness, nervousness, irritability, psychiatric disorders (serious mental illness with impaired control over one's behavior and actions, psychosis), and behavioral changes. These side effects are more common in children.

**Very rare (affects less than 1 in 10,000 people):** Taste disturbances (dysgeusia), nausea, tongue pain (glossodynia), inflammation of the oral mucosa (stomatitis), dry mouth, back pain.

**Rare serious allergic reactions:** If you experience itching, an allergic reaction with skin redness, swollen face, very low blood pressure, or irregular heartbeat (anaphylactic reaction), swelling of the face, eyes, lips, tongue, throat, or breathing difficulties (angioedema), immediate and delayed allergic reactions shortly after taking a dose, do the following: Stop using this medicine.

Seek immediate medical advice.

**Shortness of breath immediately after a dose:** In rare cases, inhalation medicines can cause an immediate increase in wheezing and shortness of breath (bronchospasm) shortly after use. If this happens:

**Stop using this medicine.**

Take a fast-acting bronchodilator to treat your symptoms.

**Seek immediate medical advice**.

**Use of high doses of inhaled corticosteroids for a prolonged time can cause systemic effects:** In rare cases, delayed growth in children and adolescents and adrenal suppression (adrenal insufficiency) can occur, and very rarely, a decrease in bone mineral density (thinning of the bones).

Sleep disturbances are more common in children, but the frequency is unknown.

**Reporting of side effects**: If you experience any side effects, contact your doctor or pharmacist. This also applies to possible side effects not mentioned in this leaflet. You can also report side effects directly to the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help gather more information about the safety of this medicine.

**How to store this medicine?**

* + Keep out of sight and reach of children.
  + Do not use this medicine after the expiry date stated on the label and box after "EXP". The last day of that month is the expiry date.
  + Store below 25°C.
  + The aerosol can is pressurized. Do not puncture or expose to heat, even when the can is empty. Do not freeze or expose to direct sunlight