Package leaflet: Information for the patient

Budesonid Zentiva 0.25 mg/mL nebuliser suspension
Budesonid Zentiva 0.5 mg/mL nebuliser suspension

budesonide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What <Invented name> is and what it is used for

<Invented name> belongs to a group of drugs called corticosteroids (cortisone). They are used to reduce inflammation.

<Invented name> is used to:
- treat, reduce and prevent inflammation of the respiratory tract in asthma,
- treat symptoms of chronic obstructive pulmonary disease (COPD) by reducing inflammation in the airways,
- treat very severe false croup (inflammation of the larynx that can cause difficulty breathing).

<Invented name> should not be used as a substitute for your bronchodilator medicine.

2. What you need to know before you use <Invented name>

Do not use <Invented name>
- if you are allergic to budesonide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using **<Invented name>** if you:
- have or have had a liver disease or problem with your liver,
- have pulmonary tuberculosis (active or inactive),
- have a fungal or viral infection of the respiratory tract.

If you switch from cortisone tablets to **<Invented name>**, on some occasions your previous allergic symptoms, such as rhinitis and eczema, may come back. You may also feel fatigue, headaches, muscle and joint pain, and sometimes nausea and vomiting. This is because the total

amount of cortisone produced by the body is reduced by using cortisone tablets for a long time. These problems will usually disappear after some time of continued <Invented name> treatment, but if your symptoms are severe contact your doctor **immediately**.

You should rinse your mouth with water after each dosing session, to minimize the risk of getting a fungal infection of the oral cavity and throat. Contact your doctor if you experience symptoms of a fungal infection.

In rare cases, with long-term treatment with <Invented name>, growth in children and adolescents may be reduced. If your child uses this medicine for a long time, the doctor will usually want to check the child's height regularly.

If your asthma worsens, you should consult a doctor. This may mean that the dosage needs to be changed or that you need a different treatment.

In the event of an acute asthma attack, you must use your fast-acting bronchodilator medication.

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

Children and adolescents
A doctor should regularly check the height of children receiving prolonged treatment with <Invented name>. If growth is slowed, therapy should be re-evaluated.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

This is because certain medicines can affect or be affected by treatment with <Invented name>, for example those containing:

- ketoconazole or itraconazole (found in medicines for fungal infections).
- saquinavir, indinavir, ritonavir, nelfinavir, amprenavir, lopinavir, fosamprenavir, atazanavir or tipranavir (so-called HIV protease inhibitors used against HIV).

<Invented name> may affect a test done to check the function of the pituitary gland, the ACTH stimulation test, to give incorrectly low values.

Pregnancy and breast-feeding
Experience with use during pregnancy does not indicate any increased risk of malformations. However, talk to your doctor before using <Invented name> during pregnancy, as the severity of asthma may change and treatment may need to be adjusted.

Budesonide passes into breast milk. However, at therapeutic doses of <Invented name>, effects on breast-fed infants are considered unlikely. <Invented name> can be used during breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
<Invented name> does not affect your ability to drive or use machines.

3. How to use <Invented name>

Always use this medicine as directed by your doctor. Ask your doctor or pharmacist if you are not sure.

Your doctor will tell you how much to take. This will depend on how severe your disease is.

You should use <Invented name> every day, or as directed by your doctor, even if you have no asthma symptoms.

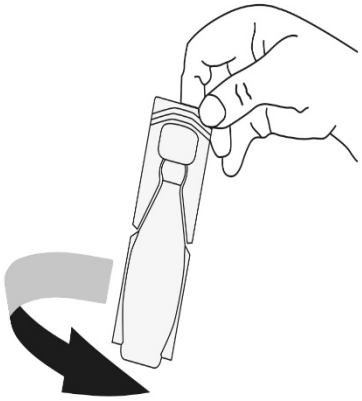
<Invented name> is inhaled using a nebulizer (an inhalation device). When you breathe in through the mouthpiece or face mask, the medicine follows the inhaled air down to the airways. It is therefore important that you inhale with even and calm breaths when taking your dose - see the user instructions.

Instructions for using the nebuliser.

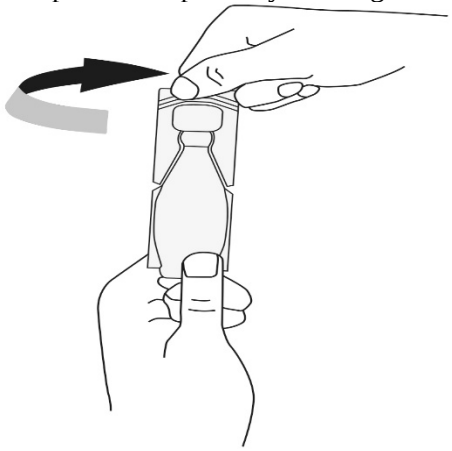
<Invented name> should only be used in a special inhalation device called a nebulizer.

Instructions for using **<Invented name>** ampoules

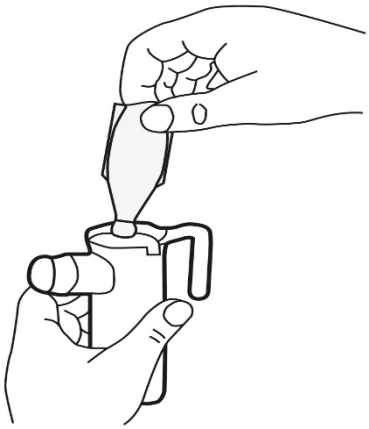
1. Break off the required number of ampoule(s) from the strip. Leave the rest in the foil envelope to protect them from the light.
2. Shake the ampoule(s) gently for 30 seconds.



3. Hold the ampoule upright. Open the ampoule by twisting off the top of the ampoule(s).



4. Pour the quantity of medication prescribed by your doctor into the nebuliser chamber. The single-dose container is marked with a line. If only 1 mL is to be used, the single-dose container held upside down is emptied until the liquid level reaches the line.



5. Use your nebuliser according to the manufacturer's instructions and as advised by your doctor.
6. Throw away the used ampoule(s) . If any unused contents remain in the ampoule they may be used within 12 hours of opening the ampoule.
7. Using a face mask or mouthpiece, breathe in the nebuliser mist calmly and deeply while sitting or standing in an upright position. If you are using a face mask, make sure that the mask fits tightly. For children, a face mask can be used to make it easier for the child to cope with inhalation.
8. Rinse your mouth with water. Spit out the water. Do not swallow it. If you have used a face mask, wash your face as well.
9. After each use, you must wash the nebuliser medication reservoir and mouthpiece (or face mask) with a mild detergent and rinse well and dry. Please refer to the nebuliser instructions on cleaning and disinfecting the nebuliser.

The opened single-dose container should be used within 12 hours and stored away from light prior to use.

Since there should always be at least 2 mL in the nebulisation chamber at the start of nebulisation, if you should only inhale 1 mL of <Invented name>, you should dilute this with saline (sodium chloride 9 mg/mL [0.9%] solution for injection).

If you use more <Invented name> than you should
If on one occasion you have used a larger dose than your doctor prescribed, you are unlikely to suffer any side effects. If, on the other hand, you use a larger dose than prescribed by your doctor for a longer period (months), there is a risk that you will suffer side effects.

If you have ingested too much medicine or if, for example, a child has accidentally ingested the medicine, contact a doctor or hospital for an assessment of the risk and advice.

It is important that you take the dose as stated on the label on the package or as your doctor has informed you. Do not increase or decrease the dose without consulting a doctor.

If you forget to use <Invented name>
If you forget to take a dose, take the next dose as usual. Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Common (may affect up to 1 in 10 people)
- Pneumonia (in COPD patients).

Tell your doctor if you have any of the following symptoms while taking <Invented name> as they may be symptoms of pneumonia:
- fever or chills
- increased mucus production, changed colour of the mucus
- increased coughing or increased breathing difficulties.

Rare (may affect up to 1 in 1,000 people)
- Angioedema (swelling around the eyes, lips, genitals, hands or feet or other body parts), anaphylaxis (swelling of lips and tongue, throat tightness, difficulty breathing, feeling faint), bronchospasm (spasm of the muscles of the airways).

Stop taking **<Invented name>** and contact your doctor immediately if you experience any of the following symptoms which may be related to angioedema, anaphylaxis or bronchospasm:
- swelling of the face, tongue or throat
- difficulty swallowing
- difficulty breathing
- hives

Other side effects
Common (may affect up to 1 in 10 people)
- Throat irritation, cough, thrush (a fungal infection of the mouth and/or throat). Thrush is less likely if you rinse your mouth out with water after using <Invented name>.

Uncommon (may affect up to 1 in 100 people)
- Blurred vision, cataract (clouding of the lens of the eye), depression, anxiety, muscle spasms, tremors.

Rare (may affect up to 1 in 1,000 people)
- Immediate and delayed allergic reactions such as hives and other skin rashes

- Corticosteroid effects. Inhaled corticosteroids can affect the normal production of steroid hormones in the body, especially if you use high doses for a long time. The effects include:
    - Changes in bone mineral density (thinning of the skeleton).
    - Glaucoma (increased pressure in the eye).
    - A reduced growth rate in children and young people.
    - An inhibition of the function of the adrenal glands (a small gland that sits next to the kidney).

The likelihood of these effects occurring is much less with inhaled corticosteroids than with cortisone tablets.

- Bruises, dysphonia (speech difficulties), hoarseness, restlessness, behavioural disturbances (predominantly in children).

Not known: frequency cannot be estimated from the available data
- sleeping problems
- aggressiveness, feeling very agitated and/or irritability.
- glaucoma (increased pressure in the eye)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*.

5. How to store <Invented name>

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 ampoule, the pouch and the carton. The expiry date refers to the last day of that month.

Do not freeze.
Store in the original package in order to protect from light.

Shelf life of ampoules after first opening the sachet: 3 months.
Shelf life of opened single-dose containers: 12 hours. Note that if only 1 mL has been used, the remaining volume is not sterile.
After dilution of the medicinal product with saline 9 mg/ml (0.9%), the diluted mixture should be used within 30 minutes.

This medicinal product does not require any special temperature storage condition.

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.

6. Contents of the pack and other information

What <Invented name> contains

- The active substance is budesonide.
  <Invented name> 0.25 mg/mL: Each ampoule of 2 mL contains 0.5 mg of budesonide.
  <Invented name> 0.5 mg/mL: Each ampoule of 2 mL contains 1 mg of budesonide.
- The other ingredients are disodium edetate E385, sodium chloride, polysorbate 80 E433, citric acid anhydrous E330, sodium citrate E331, hydrochloric acid and sodium hydroxide for pH adjustment and water for injections.

What <Invented name> looks like and contents of the pack

- Each ampoule contains 2 mL of a white to off-white suspension.
- The ampoules are packed in strips of 5 inside a sealed aluminium foil pouch (PET/Alu/PE).
- Pack sizes: each carton contains 10, 20, 40, 60, 80 and 120 ampoules. Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
<To be completed nationally>

This medicine is authorised in the Member States of the European Economic Area under the following names:
Sweden, Norway: Budesonid Zentiva
Poland: Ondemet

This leaflet was last revised 2025-04-17