

Package leaflet: Information for the user

Budesonide Azure 0.5 mg/2 ml Nebuliser Suspension **Budesonide Azure 1 mg/2 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Budesonide is and what it is used for
2. What you need to know before you use Budesonide
3. How to use Budesonide
4. Possible side effects
5. How to store Budesonide
6. Contents of the pack and other information

1. What Budesonide is and what it is used for

The name of your medicine is Budesonide Azure 0.5 mg/2 ml or 1 mg/2 ml Nebuliser Suspension (called 'Budesonide' in this leaflet).

Budesonide belongs to a group of medicines called 'corticosteroids'. It works by reducing and preventing swelling and inflammation in your lungs.

Budesonide is used to treat asthma. It is also used to treat croup in infants and children.

This medicine can be used in adults, adolescents, children and infants aged 3 months and older.

2. What you need to know before you use Budesonide

Do not use Budesonide

- 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, pharmacist or nurse before using budesonide if:

- you have or have ever had tuberculosis (TB).
- you have a cold or chest infection.
- you have liver problems.
- you have an infection of the airways.
- you have any current infections.

If you switch from steroid tablets to Budesonide, 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. These problems will usually disappear after some time of continued treatment, but if your symptoms are severe contact your doctor immediately.

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

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.

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

Patients with COPD taking this medicine may be more likely to develop pneumonia, especially patients who are elderly, smoke, have a low body mass index, or have severe COPD.

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

In rare cases, with long-term treatment with Budesonide, 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.

Other medicines and Budesonide

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Budesonide can affect the way some medicines work and some medicines can have an effect on Budesonide and your doctor may wish to monitor you carefully.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- steroid medicines.
- medicines to treat fungal infections (such as itraconazole and ketoconazole).
- medicines used to treat the HIV infection (such as ritonavir or cobicistat-containing products).
- medicines that may be used as a form of birth control or hormone replacement therapy also known as oestrogen and contraceptive steroids.

Pregnancy, breast-feeding and fertility

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 - do not use Budesonide unless your doctor tells you to.

If you get pregnant while using Budesonide, do not stop using Budesonide but talk to your doctor immediately.

Driving and using machines

Budesonide is not likely to affect you being able to drive or use any tools or machines.

3. How to use Budesonide

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

The suspension in an ampoule must be put into a nebuliser and made into a fine mist before it can be breathed in. It is then inhaled through a face mask or mouthpiece. Instructions for using your nebuliser are given after the section 'How much to use'.

Note: Do not use an ultrasonic nebuliser with Budesonide.

Your asthma may improve within 2 days. However, it can take up to 3 to 6 weeks for the medicine to have its full effect. It is important to use Budesonide every day, even if you have no asthma symptoms at the time.

How much to use

Asthma

Your doctor will tell you how much to use. This will depend on how severe your asthma is. Your doctor may lower your dose as your asthma improves.

- The recommended starting dose in adults and children over 12 years is 1 mg to 2 mg (milligrams), twice a day.
- Children under 12 years are usually prescribed a lower dose of 0.5 mg to 1 mg, twice a day. The highest dose (2 mg per day) should only be used in this age group for limited periods of time in children with severe asthma.

Croup

The recommended dose for infants and children is 2 mg a day. This may be given all in one go, or 1 mg may be given followed by another 1 mg 30 minutes later.

Instructions for using Budesonide Nebuliser Suspension

1. Break off an ampoule from the strip. Leave the rest in the foil envelope.
2. Shake the ampoule gently.
3. Hold upright. Twist off the top of the ampoule to open.
4. Place the open end of the ampoule firmly inside the nebuliser cup. Squeeze slowly to put the liquid in the cup. The ampoule is marked with a line which shows a 1 ml volume when it is held upside down. If your doctor has told you to use 1 ml (half an ampoule) squeeze the ampoule until the surface of the liquid reaches this line.
5. Throw the empty ampoule away. Put the top back on the nebuliser cup.
6. Connect one end of the cup to the face mask or mouthpiece.
7. Connect the other end of the cup to the air pump.
8. Gently shake the cup.
9. Turn on the nebuliser and breathe in the mist calmly and deeply using the face mask or mouthpiece. If you are using a face mask, make sure the face mask fits tightly.
10. You will know when your treatment is complete because the fine mist will stop coming out of your mask or mouthpiece.
11. How long it takes to nebulise all the medicine depends on the type of equipment you use. It will also depend on the amount of medicine to be used.
12. 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.
13. After each use, you must wash the nebuliser cup and mouthpiece (or face mask) in warm soapy water and rinse well. After washing, dry these parts by connecting to the air outlet or the compressor and blow air through them.

Important information about your asthma symptoms

If you feel you are getting breathless or wheezy while using Budesonide, you should continue to use Budesonide but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- your breathing is getting worse or you often wake up at night with asthma.
- your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your condition is not being properly controlled and you may need different or additional treatment immediately.

If you use more Budesonide than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice. If you use more Budesonide than you should, contact your doctor or pharmacist for advice.

If you forget to use Budesonide

If you forget to take a dose, just take the next dose as usual. Do not take 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, pharmacist or nurse.

4. Possible side effects

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

If either of the following happen to you, stop using Budesonide and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- Sudden wheezing after inhaling your medicine. This happens very rarely, affecting less than 1 in 10,000 people.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using Budesonide.
- Mild sore throat, coughing and a hoarse voice.
- Pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking budesonide they could be symptoms of a lung infection:

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties.

Uncommon (may affect up to 1 in 100 people)

- Feeling worried, restless and nervous.
- Depression.
- Trembling and shaking.
- Cataract (clouding of the lens in the eye).
- Muscle cramps.
- Blurred vision.

Rare (may affect up to 1 in 1,000 people)

- Rash, itching, contact dermatitis (a skin problem), raised itchy rash (can be red and bumpy in appearance).
- Rash on the face after using the face mask. You can stop this from happening by washing your face after using the face mask.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Budesonide, stop using Budesonide and talk to your doctor immediately.
- Sleeping problems, aggression, over-excited or irritable. These effects are more likely to occur in children.
- Bruising of the skin.
- Loss of voice.
- Hoarse voice (rare in children).
- Behavioural changes (mainly in children).
- Feelings of extreme restlessness accompanied by an increase in motor activity including muscle spasms, tremors and twitching, pacing, crossing and uncrossing the legs and other nervous activity.

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- changes in bone mineral density (thinning of the bones)
- glaucoma (increased pressure in the eye)

- a slowing of the rate of growth of children and adolescents (rare). Height of children should be regularly monitored
- an effect on the adrenal gland (a small gland next to the kidney) (rare).

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

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: HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Budesonide

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 carton, foil sachet and ampoule after 'EXP'. The expiry date refers to the last day of that month.

Store the ampoules in the original carton and foil sachet in order to protect from light. Once a foil sachet has been opened, the ampoules inside should be used within 3 months.

Note: It is best to mark the opening date on the foil sachet to help you remember. The ampoules are for single-use only. After use, any remaining contents should be thrown away.

Store units in an upright position and protect from freezing.

Do not refrigerate.

The colour of Budesonide Nebuliser Suspension is white/off-white. Do not use this medicine if you notice that the suspension is discoloured or if the container is damaged.

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 Budesonide contains

- The active substance is budesonide.
Budesonide Azure 0.5 mg/2 ml Nebuliser Suspension contains 0.5 mg of budesonide in each single-dose 2 ml ampoule.
Budesonide Azure 1 mg/2 ml Nebuliser Suspension contains 1 mg of budesonide in each single-dose 2 ml ampoule.
- The other ingredients are disodium edetate, sodium chloride, polysorbate 80, citric acid, sodium citrate and water for injections.

What Budesonide looks like and contents of the pack

The ampoules are single-dose plastic units containing 2 ml of sterile suspension. This suspension is white to off-white in colour. The suspension must be nebulised (made into a fine mist) before it can be breathed in.

Budesonide Azure Nebuliser Suspension is packed in strips of 5 ampoules inside a foil sachet. Each carton contains 20 ampoules.

Marketing Authorisation Holder

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

Manufacturer

Genetic S.p.A., Contrada Canfora, Fisciano, 84084, Italy.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland Budesonide Azure 0.5 mg/2 ml & 1 mg/2 ml Nebuliser Suspension
Malta Budesonide Azure 0.5 mg/2 ml & 1 mg/2 ml Nebuliser Suspension

This leaflet was last revised in January 2026.