

Package leaflet: Information for the user

Budesonide 1mg nebuliser suspension

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.

The name of your medicine is Budesonide 1mg nebuliser suspension but will be referred to as Budesonide throughout this leaflet. Please note that this leaflet also contains information about the other strength Budesonide 0.5mg nebuliser suspension.

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

Budesonide belongs to a group of steroids called glucocorticoids which can be used to reduce or prevent inflammatory reactions (inflammation) in the lungs.

Your medicine is used for the treatment of asthma. It is used in patients where other types of inhaler, such as a pressurised inhaler or an inhaler containing a dry powder are unsatisfactory or inappropriate.

This medicine may also be used for the treatment in hospitals of very serious cases of pseudocroup (a disease of the throat that may cause difficulty in breathing).

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 or pharmacist before using Budesonide if you:

- have or have had tuberculosis
- have or have had a liver disease or problems with your liver
- have a fungal, viral or other infection of the airways, e.g. a cold or chest infection.

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

If you are switching from corticosteroid tablets (such as prednisolone) to Budesonide, you may feel generally unwell during the switch. It is also possible that you may get symptoms that were suppressed by the corticosteroid tablets, such as allergic rhinitis (itchy, blocked or runny nose), eczema (dry, itchy skin), muscle and joint pain. You should talk to your doctor if this happens to you.

Budesonide is not suitable for use in an attack of acute shortness of breath. The sudden attack of breathlessness should be treated with a short-acting bronchodilator agent.

If you experience more wheezing and/or shortness of breath immediately after using Budesonide, you should immediately stop using Budesonide and seek medical advice.

To reduce your risk of getting oral thrush (white patches on the tongue or in the mouth), rinse your mouth with water (spit out the water – do not swallow it) and brush your teeth after using Budesonide. Tell your doctor if you do get oral thrush.

Children and adolescents

In rare cases, long term treatment with budesonide can slow down the normal growth of children and adolescents. If your child uses this medicine for a long time, it is normal that the doctor will want to monitor their height on a regular basis.

Other medicines and Budesonide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Budesonide and your doctor may wish to monitor you carefully if you are taking these medicines:

- Medicines for the treatment of a fungal infection such as ketoconazole or itraconazole
- Some medicines for HIV such as ritonavir or cobicistat-containing products
- Other steroid medicines.

Pregnancy and 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. If you become pregnant whilst taking this medicine you should tell your doctor as soon as possible.

Driving and using machines

Inhaled budesonide has no or negligible influence on the ability to drive and use 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 solution 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 take'.

You may find that your asthma improves within 2 days, but it can take up to 4 weeks before the full effect is achieved. It is important that you keep taking your medicine as instructed by your doctor even if you feel better.

How much to take

Asthma

Your doctor will tell you how much to take. 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 1mg to 2mg (milligrams), twice a day.

Children under 12 years are usually prescribed a lower dose of 0.5mg to 1mg, twice a day.

Croup

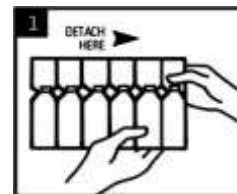
The recommended dose for infants and children is 2mg a day. This may be given as a single dose or as two 1mg doses separated by 30 minutes. The treatment can be repeated every 12 hours as necessary until improvement is seen, for a maximum of 36 hours.

Instructions for use

Your medicine must be used with a jet nebuliser. The 'mist' produced is then inhaled through a mouthpiece or face mask. Ultrasonic nebulisers should not be used with this medicine.

To take your medicine follow these steps:

1. Break off a single ampoule from the strip, leaving the rest in the foil sachet (see diagram 1)
2. Shake the ampoule gently
3. Open the ampoule by twisting off the top (see diagram 2)
4. Squeeze all of the liquid from the ampoule into the nebuliser cup. Replace the top of the nebuliser cup and dispose of the empty ampoule carefully
5. Connect one end of the cup to the mouthpiece or face mask and the other end to the air pump
6. Gently shake the cup once more then turn on the nebuliser. Breathe in the 'mist' calmly and deeply using the mouthpiece or face mask
7. When no more mist comes out of the mouthpiece or face mask, your treatment is complete



8. Rinse your mouth with water (spit out the water—do not swallow it) and brush your teeth. If you have used a face mask, you should also wash your face well. It is important to do this as it can reduce the risk of some side effects associated with this medicine
9. You should clean the nebuliser after each use. Wash the nebuliser container and mouthpiece or face mask in warm water using a mild detergent in accordance with the manufacturer's instructions. The nebuliser should then be rinsed well and dried by connecting the nebuliser container to the air pump.

It is important that you always follow the manufacturer's instructions that come with the nebuliser. If you are not sure about how to use the nebuliser, talk to your doctor or pharmacist.

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

Contact your doctor or pharmacist as soon as possible. Remember to take the pack and any remaining ampoules with you. 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 forget to use your Budesonide

Do not take a double dose to make up for a forgotten dose. Simply take your next dose on time.

If you stop using Budesonide

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.

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

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

- Signs of an **allergic reaction** which may include the following: swelling of your face, particularly around your mouth (with possible swelling of the lips, tongue, eyes and ears), rash, itching, contact dermatitis (a skin problem), hives and bronchospasm (tightening of the muscles in the airways which causes wheezing).
- Sudden wheezing and/or shortness of breath after inhaling your medicine.

Other possible side effects:

Common (may affect up to 1 in 10 people):

Soreness and/or irritation in the mouth (including oral thrush), a mild sore throat, coughing or 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):

Cataracts (clouding of the lens in the eye), depression or feeling anxious, muscle spasms, trembling and shaking, blurred vision.

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

Rash on the face after using the face mask. You can stop this from happening by washing your face after using the face mask. Bruising of the skin, aggression, increased motor activity (difficulty to stay still), sleeping problems, feeling restless, nervous, over-excited or irritable (these effects are more likely to occur in children), loss of voice, hoarse voice (in children).

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:

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

- a slowing of the rate of growth of children and adolescents. If high doses are given over several years, final height may be reduced by about 1cm
- an effect on the adrenal gland (a small gland next to the kidney).

Not known (frequency cannot be estimated from the available data):

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

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Budesonide

Keep out of the sight and reach of children.

Store in the original package in order to protect from light and moisture.

Once you have opened a single ampoule it should be used within 12 hours. After this time, the ampoule and any remaining contents should be thrown away.

Once a foil sachet has been opened the ampoules inside should be used within 3 months (it is a good idea to mark the opening date on the foil sachet to help you remember).

Do not use the suspension after the expiry date which is stated on the carton and foil labels after 'Exp'. The expiry date refers to the last day of that month.

If the ampoules show any signs of damage, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Budesonide contains

The active ingredient is Budesonide.

Each 2ml ampoule contains 1mg budesonide. The other ingredients are disodium edetate, sodium chloride, polysorbate 80, citric acid, sodium citrate and water for injection.

What Budesonide looks like and contents of the pack

Budesonide comes in plastic ampoules containing 2ml of white or off-white suspension to be nebulised (turned into a fine mist for inhalation). The ampoules are packed in strips of 5 inside a foil sachet which is then packed into a carton. Budesonide is available in packs containing 20 ampoules.

Manufactured by: Laboratoire Unither, 151 Rue André Durouchez, CS 28028, 80084 Amiens Cedex 2, France.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK.

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