

Package leaflet: Information for the user

Budesonide Teva Pharma 0.5 mg/2 ml Nebuliser Suspension Budesonide Teva Pharma 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 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

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2. What you need to know before you use Budesonide Teva Pharma Nebuliser Suspension
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1. What Budesonide Teva Pharma Nebuliser Suspension is and what it is used for

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

This medicine can be used in adults, adolescents, children and infants aged 6 months and older.

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.

Budesonide Nebuliser suspension can also be used to treat very serious pseudocroup (laryngitis subglottica) in infants and children who are in hospital.

Budesonide Nebuliser suspension can also be given for the treatment of lung attacks in chronic obstructive pulmonary disease (COPD) as an alternative to systemic (oral and/or injection) anti-inflammatories, only after suitable training in the use of this nebulised medicine has been provided and for no longer than 10 consecutive days.

2. What you need to know before you use Budesonide Teva Pharma Nebuliser Suspension

Do not use Budesonide Teva Pharma Nebuliser Suspension

- 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 before using Budesonide Teva Pharma Nebuliser Suspension if any of the following apply to you:

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

- if you experience complaints such as pain in muscles and joints, tiredness, headache, nausea and vomiting. These symptoms may occur when you have used tablets with a corticosteroid (an anti-inflammatory drug), such as prednisolone, and now switch to Budesonide Teva Nebuliser Suspension. Your doctor can then adjust the treatment if necessary;
- when switching from tablets with a corticosteroid (anti-inflammatory medicine) to Budesonide Teva Nebuliser Suspension, allergies may become apparent. This is because the tablets with an anti-inflammatory agent suppress the symptoms of allergies;
- contact your doctor if you experience blurred vision or other visual disturbances.

Budesonide Teva Nebuliser Suspension is not suitable for use in an acute attack of tightness of the chest. The acute attack of tightness of the chest must be treated with a short-acting bronchodilator. If you experience shortness of breath and wheezing immediately after administration of Budesonide Teva Nebuliser Suspension, you should stop using Budesonide Teva Nebuliser Suspension immediately and consult a doctor.

Budesonide is a steroid. You should be aware that you could fail an anti-doping test as a result of using this medicine. You should discuss this with your doctor if you have any concerns.

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.

After each inhalation, rinse your mouth with water. This reduces the risk of mouth fungus and hoarseness. If you should experience fungal infections in your mouth (white spots on the tongue or in the oral cavity) or hoarseness, please inform your doctor.

Inhalation using a mouthpiece instead of a face mask reduces the risk of facial skin irritation. If a face mask is used, the face should be washed immediately after inhalation. Alternatively, the skin covered by the face mask can be rubbed with Vaseline before inhalation (wash it off after inhalation).

If much higher doses than prescribed are used over a long period, symptoms that can also be seen when using anti-inflammatory tablets may occur, such as "full face".

Other medicines and Budesonide Teva Pharma Nebuliser Suspension

Please tell your doctor or pharmacist if you are taking or have recently taken 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 (including some medicines for HIV: ritonavir, cobicistat):

- medicines for the treatment of a fungal infection such as ketoconazole or itraconazole
- antibiotic medicines, erythromycin and clarithromycin
- other medicines which help you to breathe
- oestrogens 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 using this medicine.

Pregnancy

There is no evidence that the use of Budesonide Teva Nebuliser Suspension during pregnancy is harmful to the mother or child. It is important to treat asthma properly also during pregnancy. A worsening of the disease can be harmful to both the mother and the unborn child. As little Budesonide Teva Nebuliser Suspension as possible should be used, but the asthma must be kept under control. It is therefore recommended that you consult your doctor if you become pregnant during treatment with Budesonide Teva Nebuliser Suspension

Breast-feeding

There is no evidence that the use of Budesonide Teva Nebuliser Suspension when breast-feeding is harmful to the mother or child. If you are breast-feeding, you do not have to stop using Budesonide Teva Nebuliser Suspension.

Driving and using machines

Budesonide Teva Pharma Nebuliser Suspension does not affect the ability to drive or use machinery.

3. How to use Budesonide Teva Pharma Nebuliser Suspension

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

Your doctor will advise you of the correct dose, which will depend on how bad your asthma is.

You may find that your asthma improves within 3 days, but it can take between 2 – 4 weeks before the full effect is achieved. It is important that you keep using your medicine as instructed by your doctor even if you feel better.

The recommended doses are as follows:

Asthma

Adults (including older people) and adolescents of 12 years and over:

The usual dose is 0.5 to 2 mg of budesonide daily. This dose will normally be taken on two separate occasions during the day although if your asthma is stable and not severe your doctor may advise you to take this medicine once a day. Your doctor will tell you how and when it is best to take your medicine and you should always follow their instructions.

Infants and children (aged 6 months to 11 years)

The usual dose is 0.25 mg to 1 mg of budesonide daily. The doctor will advise you on how your child should take their medicine and this will usually be on two separate occasions during the day. However if their asthma is stable and not severe your doctor may advise that they should take this medicine once a day.

Pseudocroup

The usual dose for infants and children is 2 mg per day. This may be given as a single treatment (2 ampoules of the 1 mg/2 ml presentation) or 1 mg may be given followed by another 1 mg 30 minutes later. Dosing can be repeated every 12 hours up to a maximum of 36 hours or until improvement.

Lung attack from COPD

The dose is 4 to 8 mg budesonide per day. Divide your dose over the day; use Budesonide Teva Nebuliser 2 to 4 times a day. Use Budesonide Teva Nebuliser until your symptoms are reduced, but not longer than 10 days in a row.

Instructions for use

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

To take your medicine, follow these steps:

1. Remove one of the sterile plastic containers (ampoule) from the labelled strip by twisting and pulling



(diagram A).

2. Shake the ampoule gently in a circular motion for about 10 seconds or until no sediment is seen.



3. Hold the ampoule upright and twist off the top (diagram B).
4. Squeeze all of the liquid from the ampoule into the nebuliser cup (diagram C). 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. If you have used a face mask, you should also wash your face. It is important to do this as it can reduce the risk of some side effects associated with this medicine.
9. You should clean your 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.

Your doctor may also prescribe the following

- Your doctor may consider adding steroid tablets to your treatment during periods of stress (e.g. if you have an infection), or if you have been taking a high dose of an inhaled steroid for a long time, or before an operation.

- If you have been taking steroid tablets for your asthma, your doctor may reduce the number of tablets that you take once you start to use Budesonide Teva Pharma Nebuliser Suspension. You might experience some symptoms as a result of this including a stuffy or runny nose, a lack of energy, depression, eczema (a type of skin rash) and joint and/or muscle pain. If any of these symptoms bother you or persist, please contact your doctor.
- Your doctor may ask you to mix this medicine with 0.9% saline or solutions containing other active substances, which work on the respiratory system such as salbutamol, terbutaline, sodium cromoglycate and ipratropium bromide. If so follow their instructions carefully. The admixture should be used within 30 minutes. You must not mix this medicine unless specifically instructed by your doctor.

If you use more Budesonide Teva Pharma Nebuliser Suspension 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 use 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 Budesonide Teva Pharma Nebuliser Suspension

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

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

4. Possible side effects

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

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Rarely, inhaled drugs such as budesonide can cause acute wheezing and/or shortness of breath. If this occurs, stop using your medicine immediately and seek medical advice.

The following side effects have been reported;

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

- Soreness and/or irritation in the mouth (including oral thrush), throat irritation, hoarseness, difficulty in swallowing and cough.
- 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 side effects (may affect up to 1 in 100 people):

- Anxiety
- Depression
- Aggression
- Excitability
- Sleeping problems
- Tremor
- Clouding of the lens in the eye (Cataract)
- Blurred vision
- Muscle spasm

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

- Skin reactions including itching, rash, bruising, inflammation, redness of the skin and/or skin eruptions, swelling, slowing of growth in children and adolescents, hypersensitivity (an allergy to the medicine) and bronchospasm (tightening of the muscles in the airways resulting in wheezing).
- Suppression of your adrenal gland (a small gland next to the kidney) can also occur. The major symptoms of adrenal suppression include headaches, tiredness, feeling and being sick, weight loss, stomach pains and lack of appetite.
- Feeling restless, nervous and irritable (these effects are more likely to occur in children).
- Change in the voice.

Very rare side effects (may affect up to 1 in 10,000 people):

- Decrease in bone mineral density (thinning of the bones).

Side effects with unknown frequency:

- Glaucoma (increased pressure in the eye)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Teva Pharma Nebuliser Suspension

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 outer pack, sachet and ampoule after EXP. The expiry date refers to the last day of that month.

Do not freeze.

Store in the upright position.

After first opening the sachet, 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). Store the ampoule in the opened sachet. The opened sachet should be stored in the outer carton to protect from light and they should not be frozen.

Each ampoule is for single use only.

Opened ampoule: use immediately. Discard any unused portion.

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 Teva Pharma Nebuliser Suspension contains

- The active substance is budesonide.

Budesonide 0.5 mg Nebuliser Suspension contains 0.5 mg of budesonide as the active substance in each single dose 2 ml ampoule.

Budesonide 1 mg Nebuliser Suspension contains 1 mg of budesonide as the active substance in each single dose 2 ml ampoule.

- The other ingredients are Disodium Edetate, Sodium Chloride, Polysorbate 80 E433, Citric Acid Monohydrate E330, Sodium Citrate E331 and Water for Injection.

What Budesonide Teva Pharma Nebuliser Suspension looks like and contents of the pack

Your medicine comes in the form of plastic single dose ampoules containing 2 ml of a white to off white sterile suspension to be nebulised (made into a fine mist for inhalation).

Strips of 5 ampoules are packed into a foil sachet, which are then packed into a carton. There are 5, 10, 15, 20, 25, 30, 40, 50 or 60 ampoules in each carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer:

Norton Healthcare Limited t/a IVAX Pharmaceuticals UK
Runcorn
Cheshire
WA7 3FA
UK

Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren
Germany

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

Belgium	Budesonide Teva 0,125 mg/ml, 0,25 mg/ml and 0,5 mg/ml vernevelsuspensie
Denmark	Budesonide Teva Pharma
Finland	Budesonide Teva 0,5 mg/ml sumutinsuspensio Buderatio 0,25 mg/ml sumutinsuspensio
Ireland	Budesonide Teva Pharma 0.5 mg/2 ml and 1 mg/2 ml Nebuliser Suspension
Netherlands	Budesonide Teva Steri-Neb® 0,25 mg/2 ml, 0,5 mg/2 ml and 1,0 mg/2 ml, vernevelsuspensie
Norway	Budesonid Teva
Poland	Nebbud
Sweden	Budesonide Teva Pharma

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