

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Budesonide Teva 0.5 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:**

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

#### **1. What Budesonide Teva Nebuliser Suspension is and what it is used for**

Your medicine is called Budesonide Teva 0.5 mg/2 ml Nebuliser Suspension.

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

Budesonide Teva Nebuliser Suspension is used to treat asthma, which makes it difficult for you to breathe. Budesonide Teva Nebuliser Suspension is also used to treat pseudocroup in infants and children, who are in hospital.

Budesonide Teva Nebuliser Suspension is stored in a small plastic container. The liquid is put into a machine called a nebuliser. This machine turns the medicine into a fine mist, which you breathe in through a face mask or mouthpiece.

**Budesonide nebuliser suspension is not suitable for the treatment of sudden onset breathing difficulties including acute asthma attacks.**

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

##### **Do not use Budesonide Teva Nebuliser Suspension**

- if you are allergic (hypersensitive) to budesonide or any of the other ingredients in this medicine (listed in section 6).

##### **Warning and precautions**

Talk to your doctor or pharmacist before using Budesonide Teva Nebuliser Suspension if:

- you have ever had tuberculosis (TB);
- you suffer from liver disease;
- you have got a cold or chest infection;

##### **Children and adolescents**

The height of your child should be regularly measured when receiving prolonged treatment with glucocorticosteroids.

### **Other medicines and Budesonide Teva Nebuliser Suspension**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,.

Certain medicines may interact with Budesonide, in particular steroid tablets or current or recent use of medicine for fungal infections (ketoconazole or itraconazole), if possible this combination should be avoided. Other medicines that may interact with budesonide include erythromycin, ritanovir and saquinavir (used to treat infection); and cimetidine, which is used to treat stomach ulcers.

### **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.

Your doctor will advise whether you should use budesonide during pregnancy.

Budesonide should not be used when you are breast-feeding unless your doctor advises you to otherwise.

### **Driving and using machines**

Budesonide nebuliser suspension has no influence on the ability to drive or use machines.

## **3. How to use Budesonide Teva Nebuliser Suspension**

Your medicine is for inhalation use.

Your medicine must be inhaled via a nebuliser equipped with a mouthpiece or face mask. Your medicine must be used with a jet nebuliser e.g., Pari LC Plus.

**Note:** Do not use an ultrasonic nebuliser.

Always use Budesonide Teva Nebuliser Suspension exactly as your doctor has told you. The label will tell you how much to take and how often to take it. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is:

### **Asthma**

#### **Adults (including older people) and children (12 years and older):**

The usual starting dose is 0.5 to 2 mg daily. Your doctor will advise you of the correct dose. This will depend on the severity of your asthma. Once your asthma improves your doctor may reduce your dose to 0.5 mg – 1 mg daily.

#### **Children aged 6 months to 12 years:**

The usual starting dose is 0.25 mg to 1 mg daily. Children should use the nebuliser under the supervision of an adult.

If you have been taking steroid tablets for your asthma, your doctor may reduce or replace the number of tablets that you take once you start using Budesonide Teva Nebuliser Suspension.

You may find that your asthma improves within 2 days but it can take up to 4 weeks to achieve the full effect. You must continue taking your medication as instructed by your doctor – even when you feel well.

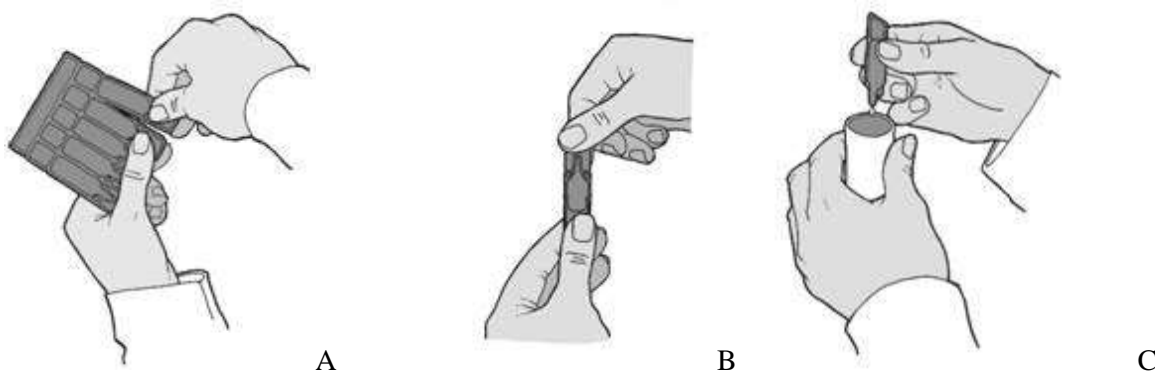
### **Pseudocroup**

The usual dose for infants and children is 2 mg a day. This may be given all in one go (4 ampoules), or 1 mg (2 ampoules) 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.

### Instruction for use

- Prepare your nebuliser for use, according to the manufacturer's instructions.
- Remove one of the sterile plastic containers (ampoule) from the labelled strip by twisting and pulling (diagram A).
- Shake the ampoule gently in a circular motion for about 10 seconds or until no sediment is seen.
- Hold the ampoule upright and twist off the cap (diagram B).
- Squeeze the contents into the reservoir of your nebuliser (diagram C).
- Following the manufacturer's instructions, use your nebuliser.
- You should rinse your mouth with water when you finish. If you have used a face mask, wash your face as well.
- After you have used your nebuliser, wash away any solution that is left in the nebuliser chamber.
- Clean your nebuliser thoroughly. Wash the mouth piece or face mask in warm water using a mild detergent. Rinse well and dry by connecting the nebuliser chamber to the compressed air inlet or compressor.

**Note:** Ultrasonic nebulisers should not be used with Budesonide Teva Nebuliser Suspension.



Do not swallow the suspension or use it as an injection.  
Each sterile ampoule is intended for single use only.

If you experience a sudden increase in wheezing after dosing, treatment with Budesonide Nebuliser Suspension should be reassessed and another treatment might be established.

#### **If you use more Budesonide Teva Nebuliser Suspension 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 accidentally take more medicine than you should have, tell your doctor immediately or go to the nearest hospital. Take this leaflet with you to show the doctor.

Never use more medicine than your doctor has told you to. Tell your doctor if your asthma gets worse or your medicine does not provide as much relief from your asthma as before.

#### **If you forget to use Budesonide Teva Nebuliser Suspension**

If you forget to take a dose at the right time, take it as soon as you remember. Do not take two doses together.

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.

Stop using Budesonide Teva Nebuliser Suspension immediately if either of the following happens to you:

- Swelling of your face, particularly around your mouth, lips, tongue, eyes and ears. Rash, itching, skin problems and tightening of your chest with difficulty in breathing. These signs mean that you are having an allergic reaction. This happens rarely, affecting up to 1 in 1 000 people.
- Sudden wheezing after you have inhaled your medicine. This happens rarely, affecting up to 1 in 1 000 people.

Other possible side effects:

Common: may affect up to 1 in 10 people:

- Irritation in the mouth and throat – this is less likely to occur if you rinse your mouth out with water after you have taken your medicine.
- Cough
- Infection in mouth and throat which may cause difficulty on swallowing

Rare: may affect up to 1 in 1 000 people:

- Skin reactions including rash, itchiness and redness
- Hoarseness
- Chest tightness and difficulty in breathing
- Swelling of the face, lips and tongue
- A slowing of the rate of growth in children and adolescents
- Restlessness, Nervousness, Behavioural changes (predominantly in children)
- An effect on the adrenal gland (a small gland next to the kidney)
- Bruising
- Voice abnormalities

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

- Glaucoma (increased pressure in your eye)
- Cataract (clouding of the lens in the eye)
- Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable (more likely to occur in children).

Tell your doctor if you are worried by any of these symptoms or if they persist.

### **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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Budesonide Teva 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 store above 25°C.

Store in the upright position.

Store the ampoule in the original package in order to protect from light.

After first opening the sachet, use within 3 months.

Any remaining suspension left in the ampoule should be thrown away immediately. Never use an ampoule if it contains discoloured or cloudy suspension, which does not disappear by shaking.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Budesonide Teva Nebuliser Suspension contains**

- The active substance is budesonide.  
Each 2 ml ampoule contains 0.5 mg Budesonide (0.25 mg/ml).
- 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 Nebuliser Suspension looks like and contents of the pack**

Each pack of Budesonide Teva Nebuliser Suspension consists of plastic ampoules containing a white to off white suspension. 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.  
Computerweg 10  
3542 DR Utrecht  
The Netherlands

#### **Manufacturer:**

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

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	Budesoteva 0,25 mg/ml vernevelsuspensie
Denmark	Budesonid Teva
Finland	Budesonide Teva 0,25 mg/ml sumutinsuspensio
Germany	Larbex 0,5 mg/2 ml Steri-Neb Suspension für einen Vernebler
Ireland	Budesonide Teva 0.5 mg/2 ml Nebuliser Suspension
Malta	Budesonide Teva 0.5 mg/2 ml Nebuliser Suspension
Netherlands	Larbex Steri-Neb 0,5 mg/2 ml vernevelsuspensie
Poland	Nebbud
Romania	Budesonide Teva 0,5 mg/2 ml Suspensie de inhalat prin nebulizator

This leaflet was last revised in 11/2014