# B. PACKAGE LEAFLET

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**BECLONEB® 400 micrograms nebuliser suspension**
**BECLONEB® 800 micrograms nebuliser suspension**

**Beclometasone dipropionate**

**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.

**In this leaflet:**



## 1. WHAT BECLONEB® IS AND WHAT IT IS USED FOR

BECLONEB® contains the active substance beclometasone dipropionate. It belongs to a group of medicines called corticosteroids which have an anti-inflammatory action reducing the swelling and irritation in the walls of the airways (e.g. nose, lungs), and so ease breathing problems.

BECLONEB® is indicated to treat asthma in adults and children up to 18 years of age when the use of pressurised or dry powder inhalers is unsatisfactory or inappropriate.
BECLONEB® is also indicated to treat recurrent wheezing in children up to 5 years of age.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE BECLONEB®

**Do not use BECLONEB®:**
- If you are allergic to the active substance or any of the other ingredients of this medicine listed in section 6.

**Warnings and precautions**
Talk to you doctor or pharmacist before using BECLONEB® if any of the following applies to you:
- You are being, or have ever been, treated for tuberculosis (TB).
- Your condition seems to be getting worse. Perhaps you are more wheezy and short of breath than usual, or your nebuliser seems to be less effective.
- Your doctor may need to increase the dose of BECLONEB® or give you a course of corticosteroid tablets, or change your treatment altogether.
- You have an infection in your chest. Your doctor may prescribe a course of antibiotics.
- If you have an infection of nasal and paranasal cavities you have to be treated with suitable therapies, although this does not represent specific contraindication to the use of BECLONEB®.

If you develop an immediate increase in wheezing, shortness of breath and cough after using BECLONEB®, you should discontinued immediately BECLONEB® and you should contact your doctor.

Immediately after inhalation the mouth should be rinsed with water to reduce the frequency of fungal infections in the mouth.

Switching from corticosteroid tablets to BECLONEB®
Switching from corticosteroid tablets to an inhaled corticosteroid treatment might make you feel generally unwell or you might develop a rash, eczema or a runny nose and sneezing (rhinitis).
You should see your doctor as soon as possible if you experience these symptoms. Do not stop treatment with BECLONEB® unless your doctor tells you to.

If you have been taking corticosteroid tablets at high doses or for a long time, your dose may be gradually reduced, approximately one week after you started treatment with BECLONEB®. During this time your doctor will monitor the level of corticosteroids in your body regularly.

If you have been treated for a long time with high doses of inhaled corticosteroid, you may require an **extra corticosteroid treatment in times of stress**. For example:

- during admission to hospital after a serious accident,
- before an operation,
- or if you have a chest infection or other serious illness.

Your doctor will decide if you need a course of corticosteroid tablets or possibly a corticosteroid injection and will also advise you as to how long you need to take the course of corticosteroid tablets and how you should reduce these as you get better.

**Children and adolescents**
If your child is below 5 years of age and is receiving prolonged treatment of recurrent wheezing with BECLONEB®, your doctor will regularly monitor his/her height to evaluate if growth impairment occurs and whether to stop the treatment.

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

Some medicines may increase the effects of BECLONEB® and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Tell your doctor if you are taking other corticosteroid medications as they may interact with BECLONEB® and could make any side effects worsening

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

Because growth retardation and damage to the unborn child cannot be excluded upon prolonged treatment with corticosteroids (such as beclometasone dipropionate contained in BECLONEB®) during pregnancy, your doctor will decide whether your disease requires treatment with BECLONEB®.

Corticosteroids pass into breast milk at low amounts. Damage to the infant is not reported to date. Nevertheless, as precautionary measure when high doses of beclometasone dipropionate are inhaled you should avoid breast-feeding for 4 h after administration.

**Driving and using machines**
BECLONEB® is unlikely to affect your ability to drive and use machines. However if you experience side effects such as dizziness and/or trembling, your ability to drive or operate machines may be affected.

## 3. HOW TO TAKE BECLONEB®

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

The starting dose should be prescribed by your doctor according to the frequency and severity of your disease. The dose may then be adjusted by your doctor until effective control of symptoms is reached.

*The recommended initial doses are:*

Adults and adolescents (from 12 years of age):

- 800-1600 micrograms twice daily which correspond to a total daily amount of 1600-3200 micrograms.

Children (up to 11 years of age):

- 400-800 micrograms twice daily which correspond to a total daily dose of 800-1600 micrograms.

BECLONEB®
Normally, a daily dose of 3200 micrograms in adults and adolescents and 1600 micrograms in children up to 11 years of age should not be exceeded.
In case of asthma disease, BECLONEB® must be used regularly on a daily basis. Your doctor will decide the duration of your treatment.

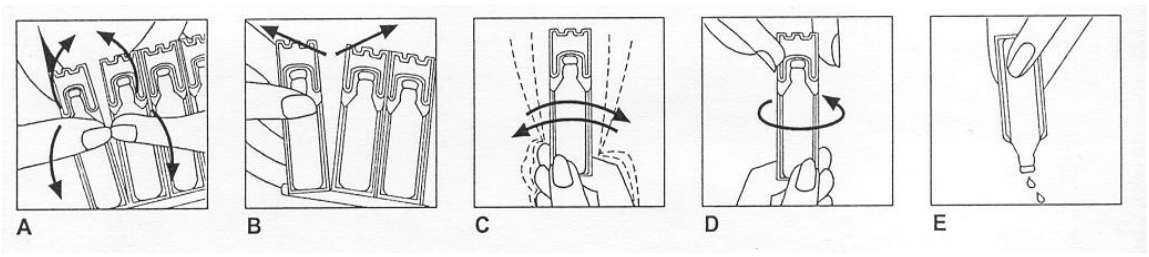
If your child suffers from recurrent wheezing, the duration of treatment should not exceed 3 months, unless otherwise prescribed by the paediatrician.

You can used BECLONEB® 800 micrograms ampoule to get 400 micrograms (half the content) using the graduation mark as described below.

Method of administration
BECLONEB® is for inhalation use only. Do not inject into a vein or use orally.

BECLONEB® must be administered by inhalation from a suitable device (jet nebuliser) according to your doctor instructions.
Use of BECLONEB® with ultrasonic nebulisers is not recommended.

Instructions for use:
Use the ampoule according to the following instructions:




1. Bend the ampoule backwards and forwards to loosen it from the strip (Figure A).
2. Carefully separate a new ampoule from the strip. Starting from the top, then in the middle (Figure B). Leave the rest in the pouch.
3. Vigorously shake and turn the ampoule upside-down in order to mix the suspension. Repeat this operation, until the whole content is fully dispersed and mixed (Figure C).

4. Open the ampoule by rotating the entrance flap as indicated by the arrow (Figure D).
5. Gently squeeze the ampoule content into the nebuliser chamber (Figure E).

The ampoule should be opened immediately before administration.
400 micrograms ampoule is for single use.
If only half dose of BECLONEB® 800 micrograms is needed, hold the ampoule upside down, ensuring that the graduation mark is clearly visible and apply moderate pressure. Carefully squeeze out the content until the level of suspension in the ampoule reaches the graduation mark and no further. Once half the content is used, reinsert the cap upside down by pushing it onto the container. The container closed in this way must be stored at 2-8 C (in the refrigerator) and the remaining quantity has to be used within 12 hours after first opening.

Dilution:
Your doctor may decide that your dose should be diluted.
In this case, empty the contents of the ampoule into the nebuliser bowl then add the quantity of sterile sodium chloride 9 mg/ml (0.9%) solution that your doctor has told you to use. Then put the top on the nebuliser bowl and shake gently to mix the contents.
The dose of nebuliser suspension may need to be diluted in order to obtain a final volume suitable for the particular nebuliser being used, to aid administration of small volumes or if a prolonged delivery time is desirable.

During nebulisation
Place the mask or mouth piece
Turn on the nebuliser.
Breathe normally. Nebulisation should not last more than 10 to 15 minutes.

After nebulisation
Do not forget to rinse the mouth, lips and the region of the face covered by the mask with water.
After inhalation, any unused suspension remaining in the nebuliser chamber must be discarded.

Cleaning:
Follow the manufacturer's instructions for cleaning your nebuliser. It is important that your nebuliser is kept clean.

**If you use more BECLONEB® than you should:**
It is important that you use your dose as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you have used more BECLONEB® than you should, tell your doctor as soon as possible. Your doctor may want to check the corticosteroid levels in your blood and therefore, may need to take a blood sample.

**If you forget to use BECLONEB®:**
If you forget to use a dose, use it as soon as you remember. If it is almost time for your next dose, do **not** use the missed dose, just use the next dose when it is due. **Do not use a double dose** to make up for a forgotten dose.

**BECLONEB®** 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.

The following side effects have been reported. Tell your doctor as soon as possible if you suffer from any of these side effects but do not stop treatment unless told to do so. Your doctor will try to prevent these effects by prescribing BECLONEB® in the lowest effective dose.

V**ery common side effects** (may affect more than 1 in 10 people):

- sore throat (pharyngitis, laryngitis). Gargling with water immediately after inhalation may help to prevent this effect.

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

- cough
- nausea (feeling sick) and stomach pains.
- thrush in the mouth, tongue and throat. Rinsing your mouth or gargling with water immediately after inhalation may help to prevent these effects.

**Uncommon side effects** (may affect up to 1 in 100 people):

- headache
- throat irritation, hoarse voice
- worsening shortness of breath, cough and wheezing (which is known as paradoxical bronchospasm). If this occurs do not take another dose of BECLONEB®. Then contact your doctor straightaway. Your doctor is likely to assess your asthma or wheezing and if necessary may start you on another course of treatment. You may be told that you should not use BECLONEB® again.

**Rare side effects** (may affect up to 1 in 1000people):

- cold sores (herpes simplex) painful blisterlike vesicles on your lips and in your mouth
- tremor (involuntary trembling)
- feeling tired.
- an allergic reaction (swelling of the eyes, face, lips and throat leading to severe difficulty in breathing, skin rashes, hives, itching or redness)

The following effects may also occur more likely in children

- Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable

At high doses over a long period of time, BECLONEB® may affect the normal production of corticosteroids in the body. Affected children and adolescents may grow more slowly than others, so it is important that they will have their height checked regularly by their doctor. Bone thinning and eye problems, which include clouding of the lens of the eye (cataract), increase in pressure in the eye (glaucoma) have been reported.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine

## 5. HOW TO STORE BECLONEB®

Keep this medicine out of the sight and reach of children.

Do not use BECLONEB® after the expiry date which is stated on the carton, pouch and ampoule.

Store the ampoules in the upright position in the original package (carton box) in order to protect from light. After first opening the pouch, write the date in the box provided on the pouch. Do not use the ampoule after 3 months from the date of first opening the pouch.
For 800 micrograms ampoule: after the first opening of the ampoule, store it in a refrigerator (2–8°C). The remaining quantity has to be used within 12 hours after first opening.

Do not use BECLONEB® if the packaging 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 BECLONEB® contains**
The active substance is beclometasone dipropionate.
Each ampoule contains 400 micrograms beclometasone dipropionate suspension in 1 ml.
Each ampoule contains 800 micrograms beclometasone dipropionate suspension in 2 ml.
The 800 micrograms ampoule has a graduation mark to indicate half the content (corresponding to 400 micrograms).

The other ingredients are polysorbate 20, sorbitan laurate, sodium chloride, water for injections.

**What BECLONEB® looks like and contents of the pack**
BECLONEB® is a white or almost white nebuliser suspension.

BECLONEB® nebuliser suspension comes in polyethylene ampoules containing 1 ml (BECLONEB® 400 micrograms) or 2 ml (BECLONEB® 800 micrograms). There are strips 5 ampoules in each sealed pouch, in pack sizes of 10 ampoules (2 pouches), 20 ampoules (4 pouches) or 40 ampoules (8 pouches).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Chiesi Farmaceutici S.p.A., 26/A Via Palermo, 43122 Parma-Italy
Manufacturer: Chiesi Farmaceutici S.p.A., 26/A Via Palermo, 43122 Parma-Italy

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

| | |
|---|---|
| Ireland | Beclospin/Becloneb |
| Germany | Sanasthmax |
| Greece | Beclospin/Becloneb |
| France | Beclospin |
| Italy | Clenil |

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