

Foster[®] NEXThaler[®] Inhalation Powder

Beclomethasone dipropionate/Formoterol Fumarate Dihydrate 100/6 mcg/dose

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What Foster[®] NEXThaler[®] is used for and how it works

Foster[®] NEXThaler[®] is a powder inhaled through your mouth and delivered deeply into your lungs, containing beclomethasone dipropionate, a glucocorticoid with anti-inflammatory action which reduces swelling and irritation in the walls of the small air passage in the lungs, and formoterol fumarate, a selective β_2 -adrenergic agonist that produces relaxation of bronchial smooth muscle in patients with reversible airway obstruction. The combination of these active substances make breathing easier by providing relief from symptoms such as shortness of breath, wheezing and cough in patients with asthma and also help to prevent asthma from worsening. Foster[®] NEXThaler[®] is indicated in the regular treatment of patients with:

- Asthma not adequately controlled with inhaled corticosteroids and "as needed" rapid-acting β_2 -agonists or
- Asthma already controlled on both inhaled corticosteroid and long acting β_2 -agonists.

- Symptomatic treatment of patients with severe Chronic Obstructive Pulmonary Disease (COPD) ($FEV_1 < 50\%$ predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators

Before you use Foster[®] NEXThaler[®]

When you must not use it:

Do NOT use Foster[®] NEXThaler[®] for acute asthma symptoms (shortness of breath, wheezing or cough) as it would not be helpful. Instead, use your 'reliever' inhaler which is a quick acting bronchodilator for relief of acute asthma symptoms.

- If you are allergic or think you are allergic to one or more of the active ingredients of Foster[®] NEXThaler[®] or if you are allergic to other medicines or inhalers used to treat asthma or to any of the other ingredients Foster[®] NEXThaler[®], contact your doctor for advice.

Before you start to use it

Take special care with Foster[®] NEXThaler[®] and always tell your doctor before using it if you have:

- Any heart problems, such as pain in the chest, recent heart attack, heart failure, narrowing of the arteries around your heart, valvular heart disease or any other known heart defects or condition where the heart muscle is abnormal.
- Arteriosclerosis, high blood pressure, an abnormal bulging of the blood vessel wall, heart rhythm

disorders such as increased or irregular heart rate, fast pulse rate or palpitations, abnormal heart trace.

- Overactive thyroid gland, low potassium blood levels, any disease of your liver or kidneys, diabetes (by inhaling high doses of formoterol, your blood glucose may increase and therefore you may need to have some additional blood tests to check your blood sugar when you start using this inhaler and from time to time during treatment).
- Adrenal gland tumour.
- You are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking Foster[®] NEXThaler[®] at least 12 hours before the anaesthesia.
- You are being, or have ever been, treated for tuberculosis or if you have a known viral or fungal infection of your chest.
- You must avoid alcohol for any reason or had any medical problems, any allergies or if you are not sure as to whether you can use Foster[®] NEXThaler[®]. Treatment with formoterol can cause a reduction in your serum potassium level

If you have severe asthma, you should take special care.

This is because a lack of oxygen in the blood and some other treatments taken together with Foster[®] NEXThaler[®] like diuretics/ 'water-tablets' or other medicines for asthma can cause a reduction in blood potassium levels. For this reason your doctor may wish to measure the potassium levels in your blood periodically.

If you take higher doses of inhaled corticosteroids over

long periods, you may have more of a need for corticosteroids in situations of stress. In this case, your doctor will decide whether you may need to increase your dose of systemic corticosteroids.

Should you need to go to the hospital, remember to take all of your medicines and inhalers with you including Foster® NEXThaler® and any medicines or tablets bought without a prescription, in their original package, if possible.

Taking other medicines

Before starting the treatment, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any other inhalers and treatments obtained without prescription.

How to use Foster® NEXThaler®

How much to use

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of Foster® NEXThaler®. He/she will adjust your treatment to the lowest dose that best controls your symptoms.

Under no circumstances: Should you change the dose without first asking your doctor.

Asthma

Adults and the elderly:

The usual dose of this medicine is one or two inhalations twice daily (4 inhalations as the maximum daily dose).

Children and adolescents aged less than 18 years old must NOT take this medicine.

COPD

Adults 18 years and above

Two inhalations twice daily.

At-risk patients:

Older people do not need to have their dose adjusted. No information is available

regarding the use of Foster® NEXThaler® in people with liver or kidney problems.

Foster® NEXThaler® is effective for the treatment of asthma in a dose of beclomethasone dipropionate which may be lower than that of some other inhalers containing beclomethasone dipropionate. If you have been using a different inhaler containing beclomethasone dipropionate previously, your doctor will advise you on the exact dose of Foster® NEXThaler® you should take for your asthma.

Remember: you should always have your quick-acting "reliever" inhaler with you at all times to treat worsening symptoms of asthma or a sudden asthma attack.

Do not increase the dose

If you feel that the medicine is not very effective, always talk to your doctor before increasing the dose.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue using Foster® NEXThaler® for as long as your doctor recommends.

If you forget to use it

Take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the correct time. **Do not double the dose.**

If you use too much (overdose)

- Contact your doctor or nearest hospital casualty department immediately for advice. Take your medicines with you so that the people can see what you have taken.
- Side effects may occur. Tell your doctor if you have any unusual

symptoms as he/she may wish to carry out further tests or decide about any measures that may be necessary.

If your asthma gets worse:

If your symptoms get worse or if you are using your "reliever" inhaler more frequently, or if your "reliever" inhaler does not improve your symptoms, you should continue to use Foster® NEXThaler® but see your doctor as soon as possible. Your doctor may need to change your Foster® NEXThaler® dose or prescribe alternative treatment.

While you are using Foster® NEXThaler® .

Things you must do

Instructions for use:

Please refer to Instructions for Use of Nexthaler Inhaler at the end of this leaflet.

Things you must not do.

Do not use beta blockers with this medicine. If you need to use beta blockers (including eye-drops), the effect of formoterol may be reduced or formoterol may not work at all. On the other hand, using drugs which work in the same way as formoterol may increase the effects of formoterol.

Things to be careful of

Using Foster® NEXThaler® together with:

- Medicines for treating abnormal heart rhythms, allergic reactions, symptoms of depression or severe mental disorders such as monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants, phenothiazines can cause some changes in the electrocardiogram. They may also increase the risk of disturbances of heart rhythm.

- Medicines for treating Parkinson's disease, an underactive thyroid gland, medicines which causes uterine contraction and alcohol can lower your heart's tolerance to formoterol.
- MAOIs, including drugs with similar properties like furazolidone and procarbazine, used to treat mental disorders, can cause a rise in blood pressure.
- Medicines for treating heart disease can cause a fall in your blood potassium level. This may increase the likelihood of abnormal heart rhythms.
- Other medicines used to treat asthma and diuretics may cause a fall in your potassium level.
- Some anaesthetics can increase the risk of abnormal heart rhythms.

Pregnancy and breast feeding

There are no clinical data on the use of Foster® NEXThaler® during pregnancy.

Foster should not be used if you are pregnant, think that you might be pregnant or are planning to become pregnant, or if you are breast-feeding, unless you are advised to do so by your doctor

Side effects

Like all medicines, Foster® NEXThaler® can cause side effects.

Common (up to 1 in 10 people):

- Trembling
- Pneumonia (in COPD patients)

Uncommon (up to 1 in 100 people);

- Cold-like symptoms, sore throat, fungal infections (of the mouth and throat), worsening of your asthma symptoms, difficulty in breathing, hoarseness, cough, unusually fast heart beat, unusually slow heart

beat, crushing chest pain, headache, feeling sick, feeling tired or nervous, changes in the electrocardiogram, low level of cortisol in your urine or in your blood, high level of potassium, glucose or fats in your blood.

Side effects which have been observed with similar medicines for inhalation containing beclomethasone dipropionate and/or formoterol are:

- Palpitations, uneven heart beat, abnormal/ impaired sense of taste, muscle pain and muscle cramps, restlessness, dizziness, feeling anxious, sleep disorders, a fall in the level of potassium in the blood.

Using high-dose inhaled corticosteroids over a long time can cause in very rare cases systemic effects: these include problems with how your adrenal glands work, thinning of the bones, growth retardation in children and adolescents, increased pressure in your eyes, cataracts, rapid weight gain, particularly on face and torso, sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable (these effects are more likely in children), abnormal behaviour.

If you experience any of the side effects above, you should contact your doctor or pharmacist immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.npra.gov.my (Consumers - > Reporting)

Storage and Disposal of Foster® NEXThaler® Storage

Keep out of the reach and sight of children.

Do not use the medicine after the expiry date which is stated on the carton, pouch and label. Expiry date refers to the last day of that month.

Store the inhaler in its original package to protect it from moisture. Only remove the inhaler from its pouch immediately before first use.

Before first opening the pouch: This medicine does not require any special temperature storage conditions.

Do not store above 30°C.

After first opening the pouch:

After first opening the pouch, the medicinal product should be used within 2 months. Use the label on the box to write down the date you open the pouch.

Disposal

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

Product description

What it looks like

The powder for inhalation is a white flowing, odourless and slightly sweet-tasting drug substance blend filled into the multi-dose inhaler device.

Ingredients

Active ingredients:

Beclometasone dipropionate, formoterol fumarate dihydrate.

Inactive ingredients:

Lactose monohydrate, magnesium stearate.

MAL number

MAL17085068AZ

Manufacturer

Chiesi Farmaceutici S.p.A. Via San Leonardo 96, 43122 Parma, Italy.

Product Registration Holder

Orient Europharma (M) Sdn Bhd.
33, Jalan Pentadbir U1/30,
Hicom Glenmarie Industrial
Park, 40150 Shah Alam,
Selangor, Malaysia

15/10/2019

Serial number:
NPRA (R1/ AI1) 25112019/016

Date of revision:

INSTRUCTIONS FOR USE OF NEXTHALER INHALER

A. Contents of the Package

This package contains:

- 1 instruction leaflet
- 1 Nexthaler inhaler inside the sealed protective pouch.

If the package contents are not the same as this, return your inhaler to the person who supplied it and get a new one.

B. General Precautions

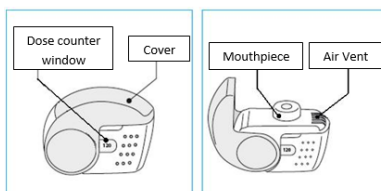
- **Do not** remove the inhaler from the pouch if you do not intend to use it immediately.
- Only use your inhaler as indicated.
- If you are not sure the dose counter has gone down by one after inhalation, wait until your next scheduled dose and take this as normal. Do not take an extra dose.
- Keep the cover closed until you need to take a dose from your inhaler.
- When you are not using your inhaler keep it in a clean and dry place.
- **Do not** attempt to take your Nexthaler inhaler apart for any reason.
- **Do not** use your Nexthaler inhaler:
 - after its expiry date
 - if it is more than 2 months since you first opened the pouch

Warnings

- if it is broken
- if the dose counter window shows “0”
- if you cannot read the dose counter window.

In these cases, dispose of your inhaler, or return it to the person who supplied it, and get a new one. Ask your pharmacist how to dispose of inhalers that are no longer required.

C. Key features of your Nexthaler inhaler

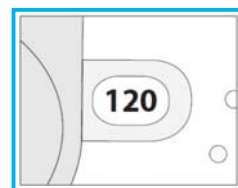


Taking a dose from your Nexthaler inhaler requires just three simple steps: Open, Inhale, Close

D. Before using a new Nexthaler inhaler

1. **Open the pouch and take out your inhaler.**
 - **Do not** use your inhaler if the pouch is not sealed or it is damaged – return it to the person who supplied it and get a new one.
2. **Inspect your inhaler.**
 - If your inhaler looks broken or damaged, return it to the person who supplied it and get a new one.
3. **Check the Dose Counter Window. If your inhaler is brand new you will see “120” in the Dose Counter Window.**

- **Do not** use a new inhaler if the number shown is less than “120” – return it to the person who supplied it and get a new one.



E. How to use your Nexthaler inhaler

E.1. Visual Check

1. **Check the number of doses left: any number between “1” and “120” shows that there are doses left.**
 - If the Dose Counter Window shows “0”, it means that there is no dose left - dispose of your inhaler and get a new one.
2. **Make sure the cover is fully closed before you use it.**

E.2. Open

1. **Hold your inhaler firmly in the upright position.**
2. **Open the cover fully.**



3. **Before inhaling breathe out as far as is comfortable.**

- **Do not** breathe out through your inhaler.

E.3. Inhale

Whenever possible, stand or sit in an upright position when inhaling.



1. Lift your inhaler up, bring it to your mouth and place your lips around the mouthpiece.

- o **Do not** cover the air vent while holding your inhaler.
- o **Do not** inhale through the air vent.

2. Take a quick and deep breath through your mouth.

- o You may notice a taste when you take your dose.
- o You may hear or feel a click when you take your dose.
- o **Do not** inhale through your nose.
- o **Do not** remove your inhaler from your lips during the inhalation.



3. Remove your inhaler from your mouth.
4. Hold your breath for 5 to 10 seconds or as long as is comfortable.
5. Breathe out slowly.

E.4. Close

1. Move your inhaler back to the upright position and close the cover fully.
2. Check that the dose counter has gone down by one.

3. If you need to take another dose, repeat steps E.1 to E.4.

F. Cleaning

- Normally, it is not necessary to clean your inhaler.
- If necessary you may clean your inhaler after use with a dry cloth or tissue.
- o **Do not** clean your inhaler with water or other liquids. Keep it dry.

G. Storage

- When you are not using your inhaler keep it in a clean dry place. You may put it back in the pouch after use.
- o **Do not** expose your inhaler to heat or direct sunlight.
- o **Do not** expose your inhaler to a humid or wet environment.
- Keep out of the sight and reach of children.
- If your inhaler has been stored for over 2 months since you opened the pouch, dispose of it and get a new one.

H. Disposal

- Dispose of your Nexthaler inhaler if the number shown in the dose counter window is "0".
- Ask your pharmacist what to do with medicines you have finished or do not need.
- o **Do not** dispose of medicines with your regular household waste.