

Foster[®] NEXThaler[®] Inhalation Powder

Beclometasone 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:

- 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

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prescription, in their original package, if possible.

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

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

Foster® NEXThaler® can be prescribed by your doctor in two different ways:

a) use Foster® NEXThaler® every day to treat your asthma together with a separate “reliever” inhaler to treat sudden worsening of asthma symptoms, such as shortness of breath, wheezing and cough

b) use Foster® NEXThaler® every day to treat your asthma and also use Foster® NEXThaler® to treat sudden worsening of your asthma symptoms, such as shortness of breath, wheezing and cough

a) Using Foster® NEXThaler® together with a separate “reliever”: Adults and the elderly:

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

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.

b) Using Foster® NEXThaler® as your only asthma inhaler:

Adults and the elderly:

The usual dose is one inhalation in the morning and one inhalation in the evening.

You should also use Foster® NEXThaler® as a “reliever” inhaler to treat sudden asthma symptoms.

If you get asthma symptoms, take one inhalation and wait a few minutes.

If you do not feel better, take another inhalation.

Do not take more than 6 reliever inhalations per day.

The maximum daily dose of Foster® NEXThaler® is 8 inhalations.

If you feel you need more inhalations each day to control your asthma symptoms, contact your doctor to seek his advice. He may need to change your treatment.

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.

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 a separate “reliever” inhaler or Foster® NEXThaler® as reliever inhaler more frequently, or if your “reliever” inhaler or Foster® NEXThaler® does not improve

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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 to be careful of

Using Foster[®] NEXThaler[®] together with:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Foster[®] NEXThaler[®] may affect the way some other medicines work. Also, some medicines can affect the way Foster[®] NEXThaler[®] works.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Some medicines may increase the effects of Foster[®] NEXThaler[®] and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- Beta-blocker medicines. Beta blockers are medicines used to treat many conditions including heart problems, high blood pressure or glaucoma (increased pressure in the eyes). If you need to use beta blockers (including eye-drops), the effect of formoterol may be reduced

or formoterol may not work at all.

- Beta adrenergic drugs (drugs which work in the same way as formoterol) may increase the effects of formoterol.
- Medicines for treating abnormal heart rhythms (quinidine, disopyramide, procainamide)
- Medicines to treat allergic reactions (antihistamines such as terfenadine)
- Medicines to treat symptoms of depression or mental disorders such as monoaminoxidase inhibitors (for example phenelzine and isocarboxazid) or tricyclic antidepressants (for example amitriptyline and imipramine) or phenothiazines
- Medicines to treat Parkinson's Disease (L-dopa)
- Medicines to treat an underactive thyroid gland (L-thyroxine)
- Medicines containing oxytocin (which causes uterine contraction)
- Medicines to treat mental disorders such as monoaminoxidase inhibitors (MAOIs), including drugs with similar properties like furazolidone and procarbazine
- Medicines to treat heart disease (digoxin)
- Other medicines used to treat asthma (theophylline, aminophylline or steroids)
- Diuretics (water tablets)

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

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

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.

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

- blurred vision

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

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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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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.
E-08, Garden Shoppe, One City,
Jalan USJ 25/1C,
47650 Subang Jaya, Selangor,
Malaysia

Date of revision:

01/07/2022

Serial number:

NPRA (R1/2) 13012023/010.

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INSTRUCTIONS FOR USE OF NEXTHALER INHALER

A. Contents of the Package

This package contains:

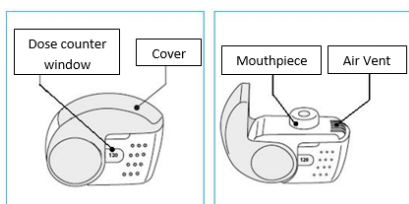
- 1 instruction leaflet
- 1 Nexthaler inhaler inside the sealed protective pouch.

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 Warnings & Precautions

- **Do not** remove the inhaler from the pouch if you do not intend to use it immediately.
- Only use your inhaler as indicated.
- 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.

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.

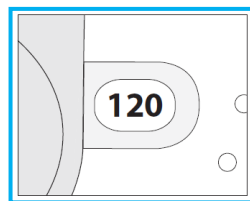
- **Use the label on the box to write down the date you open the pouch.**

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

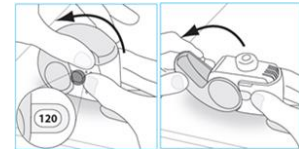
- If you are not sure you are receiving your dose correctly contact your pharmacist or doctor.
- If you are not sure the dose counter has gone down by one after inhalation, wait until your next scheduled dose and take this as normal. Do not take an extra dose.

E.1. Open

1. **Hold your inhaler firmly in the upright position.**
2. **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” there are no doses left – dispose of your inhaler and get a new one.

3. Open the cover fully.



4. Before inhaling breathe out as far as is comfortable.

- Do not breathe out through your inhaler.

E.2.

- .

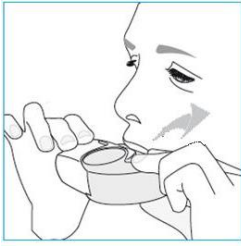
E.2 Inhale Whenever possible, stand or sit in an upright position when inhaling.

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

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

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

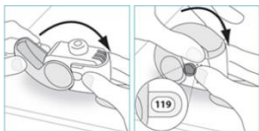
- You may notice a taste when you take your dose.
- You may hear or feel a click when you take your dose.
- **Do not** inhale through your nose.
- **Do not** remove your inhaler from your lips during the inhalation.



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

E.3. 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.3.**

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.
 - **Do not** clean your inhaler with water or other liquids. Keep it dry.

G. Storage and disposal

For information on storage conditions and disposal instructions, see section above on storage and disposal.