

# FOSTER<sup>®</sup> NEXThaler<sup>®</sup> Inhalation Powder

Beclometasone dipropionate/Formoterol Fumarate Dihydrate 200/6 mcg/dose

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## What FOSTER<sup>®</sup> NEXThaler<sup>®</sup> is used for

FOSTER<sup>®</sup> NEXThaler<sup>®</sup> is used to treat asthma in adults

## How FOSTER<sup>®</sup> NEXThaler<sup>®</sup> works

FOSTER<sup>®</sup> NEXThaler<sup>®</sup> is a powder that is inhaled through your mouth and delivered deeply into your lungs. It contains two active substances: beclometasone dipropionate and formoterol fumarate dihydrate.

- Beclometasone dipropionate belongs to a group of medicines called corticosteroids which have an anti-inflammatory action reducing the swelling and irritation in your lungs.
- Formoterol fumarate dihydrate belongs to a group of medicines called long-acting bronchodilators. These relax the muscles in your airways, widening the airways so that it is easier for you to breathe air in and out of your lungs.

These two active substances make breathing easier. They also help to prevent asthma symptoms, such as shortness of breath, wheezing and coughing.

If you are prescribed FOSTER<sup>®</sup> NEXThaler<sup>®</sup> it is likely that either:

- Your asthma is not adequately controlled by using inhaled corticosteroids and “as needed” short-acting bronchodilators or
- Your asthma is responding well to both corticosteroids and long-acting bronchodilators.

## Before you use FOSTER<sup>®</sup> NEXThaler<sup>®</sup>

### When you must not use it:

- if you are allergic to beclometasone dipropionate or formoterol fumarate dihydrate or any of the other ingredients of this medicine.

## Warnings and precautions

Do not use this medicine if you are experiencing acute asthma symptoms such as shortness of breath, wheezing and cough, your asthma is getting worse or you are having an acute asthma attack. To relieve your symptoms you should use your quick-acting “reliever” inhaler which you should carry with you at all times.

### Before you start to use it

Talk to your doctor before using FOSTER<sup>®</sup> NEXThaler<sup>®</sup> if you have any of the following:

- heart problems, these include any known disorder of your heart and/or heart function
- disorders of the heart rhythm such as increased or irregular heart rate, a fast pulse rate or palpitations, or if you have been told that your heart trace is abnormal
- high blood pressure
- narrowing of the arteries (also known as arteriosclerosis), or if you

know that you have an aneurysm (an abnormal bulging of the blood vessel wall)

- an overactive thyroid gland
- low blood levels of potassium
- any disease of your liver or kidneys
- diabetes. If you inhale 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 medicine and from time to time during treatment.
- tumour of the adrenal gland (known as a pheochromocytoma)
- you are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop taking FOSTER<sup>®</sup> NEXThaler<sup>®</sup> at least 12 hours before the anaesthesia.
- you are being, or have ever been, treated for tuberculosis (TB) or if you have a known viral or fungal infection of your chest.

## If any of the above applies to you, always inform your doctor before you use FOSTER<sup>®</sup> NEXThaler<sup>®</sup>.

If you are not sure whether you can use FOSTER<sup>®</sup> NEXThaler<sup>®</sup> talk to your doctor, asthma nurse or pharmacist before using the inhaler.

**Your doctor may wish to measure the potassium levels in your blood from time to time especially if your asthma is severe.** Like many bronchodilators FOSTER<sup>®</sup> NEXThaler<sup>®</sup> can cause a sharp fall in your serum potassium level (hypokalaemia). This is because a lack of oxygen in the blood combined with some other

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treatments you may be taking together with FOSTER<sup>®</sup> NEXThaler<sup>®</sup> can make the fall in potassium level worse.

**If you are using an inhaler to take high doses of corticosteroids over a long period of time**, you may have more of a need for corticosteroids in situations of stress. Stressful situations might include being taken to hospital after an accident, having a serious injury, or before an operation. In this case, the doctor treating you will decide whether you may need to increase your dose of corticosteroids and may prescribe some steroid tablets or a steroid injection.

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

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

## Children and adolescents

Do not give this medicine to children and adolescents aged less than 18 years.

## Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because FOSTER<sup>®</sup> NEXThaler<sup>®</sup> may affect the way some other medicines work. Also, some medicines can affect the way FOSTER<sup>®</sup> NEXThaler<sup>®</sup> 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<sup>®</sup> NEXThaler<sup>®</sup> 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 in-crease the effects of formoterol.
- Medicines for treating abnormal heart rhythms (quinidine, disopyramide, procaina-mide)
- 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.

## How to use FOSTER<sup>®</sup> NEXThaler<sup>®</sup>

FOSTER<sup>®</sup> NEXThaler<sup>®</sup> is for inhalation use.

## How much to use

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

FOSTER<sup>®</sup> NEXThaler<sup>®</sup> delivers an extrafine aerosol which results in more of each dose being delivered to your lungs. Your doctor may, therefore, prescribe a lower dose of this inhaler than your previous inhalers.

Your doctor will give you a regular check-up to make sure you are taking the correct dose of FOSTER<sup>®</sup> NEXThaler<sup>®</sup>. Once your asthma is well controlled your doctor may consider it appropriate to gradually reduce the dose of FOSTER<sup>®</sup> NEXThaler<sup>®</sup>. Under no circumstances should you change the dose without first speaking to your doctor.

## Adults and the elderly:

The recommended dose of this medicine is 2 inhalations twice daily. The maximum daily dose is 4 inhalations.

## Do not increase the dose.

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

**Remember: you should always have your quick-acting "reliever" inhaler with you at all times to treat worsening**

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## symptoms of asthma or a sudden asthma attack.

### When to use it

Use as directed by your doctor or pharmacist.

### How long to use it

Continue using FOSTER<sup>®</sup> NEXThaler<sup>®</sup> 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 take a double dose to make up for a forgotten dose.

If you stop using FOSTER<sup>®</sup> NEXThaler<sup>®</sup>:

Even if you are feeling better, do not stop using Foster or lower the dose. If you want to do this, talk to your doctor. It is very important for you to use Foster every day as prescribed by your doctor even though you may have no symptoms.

### If you use too much (overdose)

- contact your doctor or nearest hospital casualty department immediately for advice. Take your medicine 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.

## While you are using FOSTER<sup>®</sup> NEXThaler<sup>®</sup> .

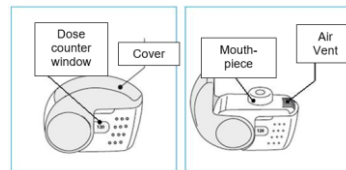
### Things you must do

#### 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 FOSTER<sup>®</sup> NEXThaler<sup>®</sup> inhaler apart for any reason.

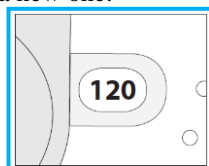
### Key features of your FOSTER<sup>®</sup> NEXThaler<sup>®</sup> inhaler



Taking a dose from your FOSTER<sup>®</sup> NEXThaler<sup>®</sup> inhaler requires just three simple steps: Open, Inhale, Close.

Before using a new FOSTER<sup>®</sup> NEXThaler<sup>®</sup> 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.

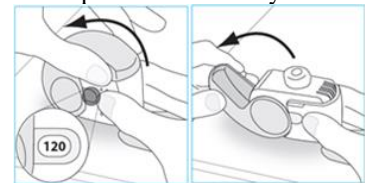


## How to use your FOSTER<sup>®</sup> NEXThaler<sup>®</sup> inhaler

- 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 Inhale

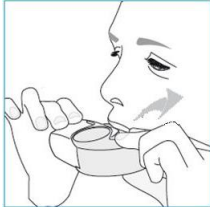
Whenever possible, stand or sit in an upright position when inhaling.

1. Lift your inhaler up, bring it to your mouth and place your lips around the mouthpiece.
  - Do not cover the air vent when 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.

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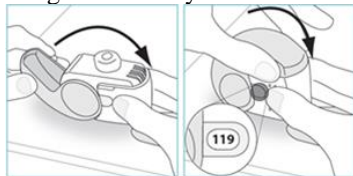
- You may hear or feel a click when you take your dose.
- Do not inhale through your nose.
- Do not remove your inhaler from your lips during the inhalation.



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.

### 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.

### Things you must not do.

Do not increase the dose.

If you feel that the medicine is not very effective, always talk to your doctor before increasing the dose. Do not stop using FOSTER<sup>®</sup> NEXThaler<sup>®</sup> abruptly.

### Things to be careful of

#### **If your breathing does not change:**

If your symptoms do not improve after inhaling FOSTER<sup>®</sup> NEXThaler<sup>®</sup>, you may be using it incorrectly. Therefore check the instructions for correct use and/or contact your doctor, nurse or pharmacist to be trained properly again.

#### **If your asthma gets worse:**

If your symptoms get worse or are difficult to control (e.g. 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<sup>®</sup> NEXThaler<sup>®</sup> but go to see your doctor as soon as possible. Your doctor may need to change your dose of FOSTER<sup>®</sup> NEXThaler<sup>®</sup> or prescribe an additional or alternative treatment.

#### **Pregnancy, breast-feeding and fertility**

There is no clinical data on the use of FOSTER<sup>®</sup> NEXThaler<sup>®</sup> during pregnancy.

If you think you are pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should only use FOSTER<sup>®</sup> NEXThaler<sup>®</sup> during pregnancy if you are advised to do so by your doctor. Your doctor will decide whether you must stop taking FOSTER<sup>®</sup> NEXThaler<sup>®</sup> during breastfeeding or you should take FOSTER<sup>®</sup> NEXThaler<sup>®</sup> but refrain from breastfeeding. Always follow the advice of your doctor strictly.

#### **Driving and using machines**

FOSTER<sup>®</sup> NEXThaler<sup>®</sup> 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 machinery may be affected.

#### **FOSTER<sup>®</sup> NEXThaler<sup>®</sup> contains lactose.**

Lactose contains small amounts of milk proteins, which may cause reactions in allergic patients. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### **Side effects**

Like all medicines, FOSTER<sup>®</sup> NEXThaler<sup>®</sup> can cause side effects.

As with other inhaler treatments there is a risk of worsening shortness of breath, cough and wheezing immediately after using FOSTER<sup>®</sup> NEXThaler<sup>®</sup> and this is known as paradoxical bronchospasm. If this occurs you should STOP using FOSTER<sup>®</sup> NEXThaler<sup>®</sup> immediately and use your quick-acting "reliever" inhaler straightaway to treat the symptoms. You should contact your doctor straightaway.

Tell your doctor immediately if you experience allergic reactions which include skin allergies, skin itching, skin rash, reddening of the skin, swelling of the skin or of mucous membranes especially of the eyes, face, lips and throat.

Other possible side effects of FOSTER<sup>®</sup> NEXThaler<sup>®</sup> are listed below according to their frequency.

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

- trembling.

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

- cold-like symptoms, sore throat
- fungal infections (of the mouth and throat). Rinsing your mouth or gargling with water and brushing your teeth immediately after inhalation may help to prevent these side effects.

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- worsening of your asthma symptoms, difficulty 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 (ECG)
- low level of cortisol in your urine or in your blood
- high level of potassium in your blood
- high level of glucose in your blood
- high level of 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 beclometasone dipropionate and/or formoterol are:

- palpitations
- uneven heart beat
- abnormal or 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
- increase/decrease of blood pressure.

Using high-dose inhaled corticosteroids over a long time can cause systemic effects; these include:

- problems with how your adrenal glands work (adrenosuppression)
- thinning of the bones
- growth retardation in children and adolescents
- increased pressure in your eyes (called glaucoma), cataracts

- rapid weight gain, particularly of the face and torso
- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur 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 calling Tel: 03-78835550, or visiting the website [portal.npra.gov.my](http://portal.npra.gov.my) (Consumers - > Reporting)

## Storage and Disposal of Foster<sup>®</sup> NEXThaler<sup>®</sup>

### Storage

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 carton, sachet and label after Exp. The expiry date refers to the last day of that month.

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

Before first opening the sachet: This medicinal product does not require any special temperature storage conditions.

After first opening the sachet: Do not store above 30°C.

After first opening the sachet, the medicinal product should be used within 2 months.

Use the label on the box to write down the date you open the sachet.

### 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

FOSTER<sup>®</sup> NEXThaler<sup>®</sup> is presented as a white to almost white inhalation powder contained in a plastic inhaler called Nexthaler. Each pack contains one inhaler which provide 120 inhalations each. The inhaler comes in a sealed protective sachet.

### Ingredients

#### **Active ingredients:**

Beclometasone dipropionate and formoterol fumarate dihydrate.

Each metered dose contains 200 micrograms of beclometasone dipropionate and 6 micrograms of formoterol fumarate dihydrate. This corresponds to a delivered dose from the mouthpiece of 158.8 micrograms of beclometasone dipropionate and 4.9 micrograms of formoterol fumarate dihydrate.

#### **Inactive ingredients:**

Lactose monohydrate, magnesium stearate.

### MAL number

MALXXXXXX

## 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.

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**Date of revision:**

29/02/2023

**Serial Number:**

NPRA (R1) 23/032