

QR code to www.oeh.fi/fgb.

See the end of this leaflet, scan this code or visit www.oeh.fi/fgb to see instructions on how to use Easyhaler

Package leaflet: Information for the user

Formoterol Easyhaler 12 micrograms/dose inhalation powder formoterol fumarate dihydrate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Formoterol Easyhaler is and what it is used for

What is Formoterol Easyhaler?

Formoterol Easyhaler is an asthma medication that opens up the airways thus preventing and treating breathing symptoms such as wheezing, shortness of breath and coughing.

The active ingredient is formoterol. Formoterol powder is packed in an inhaler called Easyhaler. You inhale the powder into your lungs through the mouthpiece of the inhaler.

What is Formoterol Easyhaler used for?

It is used:

- together with inhaled corticosteroids to treat and prevent asthma symptoms

- to treat and prevent symptoms of chronic obstructive pulmonary disease (COPD).

The effect of formoterol begins within 1–3 minutes and lasts for approximately 12 hours.

2. What you need to know before you use Formoterol Easyhaler

Do not use Formoterol Easyhaler, if you are allergic:

- to formoterol
- to the other ingredient of this medicine (listed in section 6), which is lactose monohydrate (which contains small amounts of milk protein)

Not to be given to children under the age of 6.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Formoterol Easyhaler, if you have any of the following:

- heart problems
- high blood pressure
- diabetes (you may need some additional blood sugar tests when you start using this medicine)
- low blood potassium level
- an overactive thyroid gland
- a tumour of the gland next to your kidneys (phaeochromocytoma).

Other medicines and Formoterol Easyhaler

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

In particular you need to tell your doctor, if you are taking:

- monoamine oxidase (MAO) inhibitors e.g. moclobemide for depression. Do not take Formoterol Easyhaler, if you have taken MAO inhibitors within the last 14 days.
- tricyclic antidepressants e.g. amitriptyline or imipramine.
- medicines for Parkinson's disease e.g. selegiline and levodopa
- medicines for heart conditions including an irregular heart beat or angina
- medicines for hypertension
- beta blockers (either as tablets or eye drops)
- water tablets (diuretics)
- erythromycin (used to treat infection)
- corticosteroids tablets (such as prednisolone)
- medicines for respiratory problems e.g. theophylline or aminophylline
- medicines for allergies such as antihistamines
- medicines used to treat mental illnesses or severe nausea and vomiting such as phenothiazines
- medicines for thyroid disorders e.g. levothyroxine.

If you are going to have an anaesthetic tell your doctor or dentist that you are using Formoterol Easyhaler

Formoterol Easyhaler with food, drink and alcohol

If you drink alcohol whilst using Formoterol Easyhaler, you may experience an increase in heart rate.

Pregnancy, breast-feeding and fertility

If you are pregnant, become pregnant or are planning to become pregnant, do not use Formoterol Easyhaler unless you are advised to do so by your doctor. Do not breast-feed, if you are using Formoterol Easyhaler.

Driving and using machines

Formoterol Easyhaler should not affect your ability to drive or operate machinery. However, if you experience side effects such as dizziness, your ability to drive or operate machinery may be affected.

Formoterol Easyhaler contains lactose

This medicine contains approximately 7.6 mg lactose (as monohydrate) per dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use Formoterol Easyhaler

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

Acute asthma attacks

If you get an acute asthma attack between Formoterol Easyhaler doses, you should use a short-acting “reliever” inhaler.

Contact your doctor as soon as possible if you experience any of the following:

- wheezing, shortness of breath or coughing that is worse than normal
- symptoms come back more quickly than usual
- you need to use a short-acting “reliever” inhaler more often than usually.

Use in adults (including the elderly) and adolescents (above 12 years):

Asthma:

Usually 1 dose (12 mcg) twice daily regularly. This may be increased to a maximum 2 doses (2 x 12 mcg) twice daily.

Chronic Obstructive Pulmonary Disease (COPD):

Usually 1 dose (12 mcg) twice daily regularly. The maximum daily dose is 2 doses per day.

Use in children 6 to 12 years:

Asthma:

Usually 1 dose (12 mcg) two times daily regularly. The maximum daily dose is 2 doses per day.

If you use more Formoterol Easyhaler than you should

If you take too much Formoterol Easyhaler contact your doctor or asthma nurse. Symptoms of an overdose may include nausea, vomiting, headache, tremor and fast heart beat.

If you forget to use Formoterol Easyhaler

Do not take a double dose to make up for a forgotten dose. If you miss a dose, just take one as soon as you remember. If it is almost time for your next dose, wait and take the usual amount at the right time.

If you stop taking Formoterol Easyhaler

Do not stop or reduce the dose of Formoterol Easyhaler, inhaled corticosteroid or other medicines for your breathing problems without talking to your doctor. It is important to use these medicines regularly, even when you feel better. This medicine is normally taken in the mornings and in the evenings.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

The instructions on how to use the inhaler are at the end of the leaflet.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These side effects are often mild and may go away as treatment continues. If they are severe or last for more than a few days, or if you are worried about any of them, talk to your doctor.

If you experience any of the following side effects, stop taking Formoterol Easyhaler and seek immediate medical attention:

- itching, rash, reddened skin
- swelling of the eye lids, lips, face or throat
- low blood pressure or collapse
- increase in wheezing, and shortness of breath shortly after dosing.

Other side effects:

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

- tremor
- palpitations
- headache.

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

- muscle cramps, muscle pain
- fast heart beat
- sleeplessness
- feeling nervous, restlessness.

Rare (may affect up to 1 in 1,000 people):

- irregular or uneven heart beat/extra beats
- decrease in blood potassium level
- mouth or throat irritation
- wheezing/shortness of breath
- allergic reactions
- nausea (feeling sick).

Very rare (may affect up to 1 in 10,000 people):

- taste disturbances
- increase in blood sugar
- chest pain or tightness
- heart condition (prolongation of the QT interval)
- changes in blood pressure
- dizziness.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Formoterol Easyhaler

- Keep this medicine out of the sight and reach of children.
- Before the first use store in the unopened foil bag.

- After opening the foil bag, do not store above 30°C and protect from moisture. It is recommended to keep the Easyhaler in its protective cover.
- If your Formoterol Easyhaler gets damp, you will need to replace it with a new one.
- Replace your Formoterol Easyhaler with a new one no later than 4 months after you open the foil bag. Write down the date you opened the bag to help you remember.

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

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 Formoterol Easyhaler contains

- the active substance is formoterol fumarate dihydrate
- the other ingredient is lactose monohydrate (which contains small amounts of milk protein)

What Formoterol Easyhaler looks like and contents of the pack

White to yellowish white powder in a multidose plastic inhaler. Each inhaler contains 120 doses and has a white body with green upper part. The inhaler is sealed in a foil bag and packed with or without a protective cover in a cardboard box. Formoterol Easyhaler 12 micrograms/dose inhalation powder is available in packs of 1 or 2 inhaler(s).

- one inhaler (120 doses) + protective cover
- one inhaler (120 doses)
- two inhalers (2 x 120 doses)

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Distributed in the UK by:

Orion Pharma (UK) Ltd.
Abbey Gardens
4 Abbey Street
Reading
RG1 3BA

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

Finland, Slovakia, Czech Republic,
United Kingdom, Hungary, Poland
Denmark

Formoterol Easyhaler
Formo Easyhaler

This leaflet was last revised on 26/03/2021.

Detailed and updated information on how to use this product is available by scanning this QR code (included also on outer carton and inhaler label) with a smartphone. The same information is also available on the following URL: www.oeh.fi/fgb

QR code to www.oeh.fi/fgb.

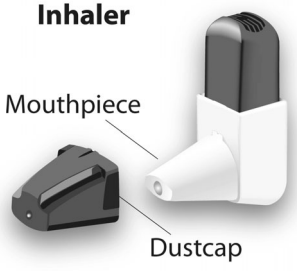
How to use the Easyhaler inhaler

About your Easyhaler

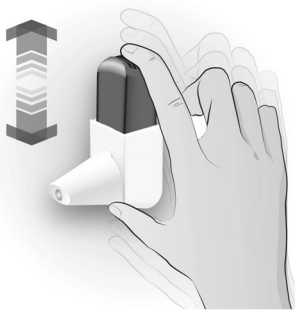
Formoterol Easyhaler may be different to inhalers you have used in the past. Therefore it is very important that you use it properly as using incorrectly can lead to you not receiving the right amount of medicine. This could make you very unwell or could lead to your asthma and COPD not being treated as it should.

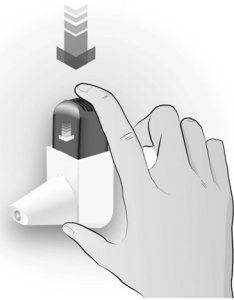
Your doctor, nurse or pharmacist will show you how to use your inhaler properly. Make sure you understand the correct way to use the inhaler. If you are unsure contact your doctor, nurse or pharmacist. As with all inhalers, caregivers should ensure that children prescribed Formoterol Easyhaler use correct inhalation technique, as described below. You can also use the instruction video at www.oeh.fi/fgb


When you first get your Easyhaler

<p>The Easyhaler comes in a foil bag. Do not open the foil bag until you are ready to start using the medicine as it helps to keep the powder dry in the inhaler.</p> <p>When you are ready to start treatment open the bag and record the date e.g., in your calendar.</p> <p>Use the inhaler within 4 months of removing from the foil bag.</p>	<p style="text-align: center;">Inhaler</p>  <p>Mouthpiece</p> <p>Dustcap</p>
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HOW TO USE CORRECTLY

<p>Step 1: SHAKE</p> <ul style="list-style-type: none">• Remove the dustcap• Shake the inhaler 3 to 5 times holding it in the upright position	<p>SHAKE x 3-5</p> 	<p>Important points to remember</p> <ul style="list-style-type: none">• It is important to keep the inhaler in the upright position• If you accidentally click while you shake the inhaler, empty the powder from the mouthpiece as shown below
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<p>Step 2: CLICK</p> <ul style="list-style-type: none"> • Keep holding the inhaler upright between your forefinger and thumb • Press down until you hear a click, and let the inhaler click back again. This releases a dose • Only click down once 	<p>CLICK x 1</p> 	<p>Important points to remember</p> <ul style="list-style-type: none"> • The inhaler will not click if the dustcap is still on • Only click down once • If you accidentally click more than once, empty the powder from the mouthpiece, see below • Click to release dose before you inhale, not at the same time • Keep the inhaler upright when you click it and when you inhale the dose. If you tip it, the powder could fall out before you are able to inhale it
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<p>Step 3: INHALE</p> <ul style="list-style-type: none"> • Keep holding the inhaler upright • Breathe out normally • Place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece • Take a strong and deep breath in • Take the inhaler out of your mouth, hold breath for at least 5 seconds, then breathe out normally. 	<p>INHALE</p> 	<p>Important points to remember</p> <ul style="list-style-type: none"> • Make sure the whole mouthpiece is well inside your mouth, so that the medication gets into your lungs • Make sure your lips make a good seal around the mouthpiece • Do not breathe out into the inhaler. This is important: it could clog up the inhaler. If you breathed out into the inhaler, empty the powder from mouthpiece, see below
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If you need to take another inhalation, please repeat the steps 1-3 Shake-Click-Inhale.

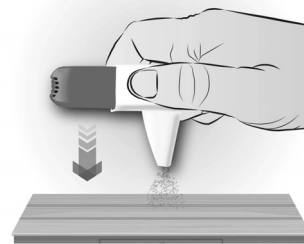
After you have used the inhaler:

- Put the dust cap back on the mouthpiece. It stops the inhaler going off by accident.

How to empty the powder from the mouthpiece

If you click the inhaler by accident, or if you might have clicked it more than once, or if you breathe out into it, empty the mouthpiece.

- Tap the mouthpiece to empty the powder onto a table top, or the palm of your hand.
- Then start again with steps Shake-Click-Inhale.



Cleaning the Easyhaler

Keep your inhaler dry and clean. If necessary you may wipe the mouthpiece of your inhaler with a dry cloth or tissue. Do not use water: the powder in the Easyhaler is sensitive to moisture.

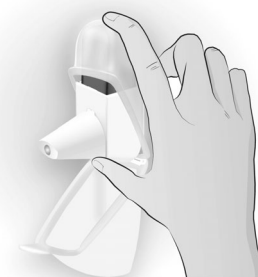
Using the Easyhaler with a protective cover

You may use a protective cover with your inhaler. This helps to improve durability of the product. When you first insert your inhaler in the protective cover make sure the dustcap is on the inhaler as this stops it going off by accident. You can use the inhaler without removing it from the protective cover.

Follow the same instructions as above, **1. Shake – 2. Click – 3. Inhale.**

Remember to:

- Keep the inhaler in the upright position when clicking it
- Replace the dustcap after taking the dose as this stops the inhaler going off by accident.

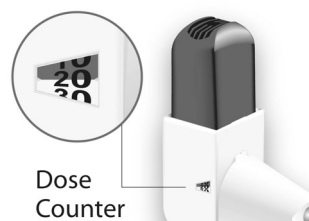


When to switch to a new Easyhaler

The dose counter shows the number of remaining doses. The counter turns after every 5th click. When the dose counter starts turning red, there are 20 doses left.

If you do not already have a new Easyhaler, contact your doctor for a new prescription. When the counter reaches 0 (zero), you need to replace the Easyhaler.

If you use the protective cover, you can keep it and insert your new inhaler into it.



Remember

- **1. Shake – 2. Click – 3. Inhale.**
- Do not get your inhaler wet, protect it from moisture.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

