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 or the other ingredient of this medicine (listed in section 6), which is lactose (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.**
Lactose contains small amounts of milk protein, which may cause allergic reaction. If you have been told that you do not tolerate certain kinds of sugars, contact your doctor before taking this medicine. The amount of lactose in Formoterol Easyhaler (approximately 8 mg per dose) does not normally cause problems in lactose intolerant people.

3. **How to use Formoterol Easyhaler**
See “Instructions for using your Easyhaler” at the end of this leaflet.

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 older people) 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.

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. 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 laminate pouch.
• After opening the laminate pouch 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 laminate pouch. Write down the date you opened the pouch 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 laminate pouch 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 and Manufacturer
This medicinal product is authorised in the Member States of the EEA under the following names:

Finland, Slovakia, Czech Republic, United Kingdom, Hungary, Poland
Formoterol Easyhaler

Denmark
Formo Easyhaler

Estonia, Latvia, Lithuania
Fomeda Easyhaler

This leaflet was last revised in 06/2015.
INSTRUCTIONS FOR USING YOUR EASYHALER

Formoterol Easyhaler is easy to use. Read through these instructions first. They tell you what you should do and what to look out for.

UNPACKING THE INHALER (Figures 1 and 2)

The inhaler (Figure 1) comes in a laminate pouch to keep the powder dry. Do not open the pouch until you are ready to start using your Easyhaler.

A protective cover is optional. If you do not use the protective cover, move on to section “Taking a dose from Formoterol Easyhaler”.

Open the protective cover and insert the inhaler into it (Figure 2). Make sure the dust cap covers the mouthpiece of the Easyhaler (this stops the inhaler releasing medicine by accident).

If you are not using the inhaler immediately, close the protective cover.

Taking a dose from Formoterol Easyhaler

If you use the protective cover with your Formoterol Easyhaler, open it.

Remove the dust cap.

A. Shake (Figure 3a or 3b)
Shake the inhaler vigorously up and down 3–5 times, to allow proper powder flow and a correct dose. After shaking, hold the Easyhaler in the upright position.

B. Click (Figure 4a or 4b)
Press the inhaler once between your index finger and thumb until you hear a click, and let it click back again to deliver powder into the inhalation channel inside the mouthpiece. Keep holding the inhaler in the upright position.

If you think that you have clicked the Easyhaler more than once, see “NOTE!” (Figure 6a or 6b) below.

C. Inhale (Figure 5a or 5b)
In the sitting or standing position
- breathe out normally (but NOT into the inhaler)
- place the mouthpiece in your mouth between your teeth and seal your lips tightly around it
- take a strong and deep breath through the inhaler (Figure 5a or 5b)
- remove the inhaler from your mouth
- hold your breath for at least 5 seconds, then breathe normally.

Make sure that you do not breathe out into the inhaler, because...
it could clog up the inhaler. If this happens, see “NOTE!” (Figures 6a or 6b) below.

If you have been prescribed more than one dose, pause for one minute and repeat points A, B and C.

Put the dust cap back on the mouthpiece.

Close the protective cover, if you are using it.

**NOTE!** (Figures 6a or 6b)

If you click the inhaler by accident, or if you have clicked it more than once, or if you breathe out into it, tap the mouthpiece to empty the powder onto a table top or the palm of your hand (Figure 6a or 6b). This ensures proper dosing. Then start again with steps A, B and C.

**CLEANING**

Clean the mouthpiece at least once a week with a clean dry cloth or tissue. Do not use water or other liquids, the powder in the inhaler is sensitive to moisture.

If you use the protective cover, you can take the inhaler out of it to wipe it. When you are putting it back into its protective cover, put the dust cap on the mouthpiece to stop it releasing the medicine accidentally.

**GETTING A NEW FORMOTEROL EASYHALER** (Figures 7a, 7b and 8)

Replace your Easyhaler with a new one 4 months after you opened the laminate pouch. Write down the date you opened the pouch to help you remember.

The inhaler has a dose counter which shows how many doses are left (Figure 7a or 7b). The counter turns after every fifth dose (actuation). When the numbers turn red, there are 20 doses left. If you do not already have a new inhaler, contact your doctor for a new prescription. When the counter reaches 0, you need to replace the inhaler even though you can still observe the powder in the clear window on the back of the inhaler (Figure 8).

If you use a protective cover, keep it for the next inhaler.