Package leaflet: Information for the patient
FORMOTEROL 12 MICROGRAMS INHALATION POWDER, HARD CAPSULE
Formoterol Fumarate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What FORMOTEROL is and what it is used for

Formoterol contains the active substance formoterol fumarate.

Formoterol is one of a group of medicines called selective beta-2-adrenoreceptor agonists.
Formoterol is used for prevention of induced-exercise asthma, treatment of symptoms of bronchial asthma and other chronic obstructive reversible pulmonary diseases such as coughing or breathing difficulties and for symptomatic long-term treatment of bronchial asthma in combination with a long-term anti-inflammatory therapy (eg. Corticosteroids).

2. What you need to know before your take FORMOTEROL

Follow carefully the instructions of your doctor or pharmacist even if those are different from the instructions given in this leaflet.

Do not take Formoterol
- If you are allergic to formoterol, to beta 2 agonist general or to lactose (which contains small amount of milk proteins) or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions Formoterol

Talk to your doctor or pharmacist before taking Formoterol

- If you suffer from any heart problem: ischaemic heart disease (reduced blood supply to the heart muscle), cardiac arrhythmias (abnormal changes in heartbeat frequency), severe heart decompensation (defective cardiac filling and /or impaired contraction and emptying), subvalvular aortic stenosis (narrowing of aorta in the region under aortic valve), hypertrophic obstructive cardiomyopathy (thickness in the cardiac muscle that cause obstruction of the outflow of blood), aneurysm.

- If you suffer from hypertension (high blood pressure)
- If you suffer from hyperthyroidism (which causes loose of weight despite increased appetite).
- If you have confirmed or suspected prolongation of QT interval (abnormal change in the heartbeat frequency).
- If you suffer from diabetes, as blood glucose should be more often checked.
- If you suffer from acute severe asthma (a chronic condition involving the respiratory system that causes symptoms such as wheezing, shortness of breath, chest tightness, and coughing), as the risk of suffering a decrease in the level of potassium in blood is increased.
- When used to treat asthma, Formoterol is usually only prescribed if other types of asthma medicines are insufficient and Formoterol is usually prescribed along with other types of asthma medicines.
- Treatment with Formoterol is usually not started when the symptoms of asthma have gotten much worse in a short period.
- If paradoxical bronchospasm arises, Formoterol should be immediately discontinued. This adverse reaction causes difficulty breathing, thorax pain and coughing.
- In the event of premature birth or threatened abortion, as Formoterol should not be used in these cases.
- During the labour, because it causes relaxation of the smooth musculature in the uterus.
- Along the treatment, as it should be supplemented with an anti-inflammatory preparation for inhalation or oral corticosteroid.
- If you suffer from hypokalaemia (decrease of level of potassium in blood).
- If you are being treated for phaechromocytoma (tumour of the medulla of the adrenal glands).

Contact your doctor immediately if your experience serious side effects of if you feel that your breathing is getting worse. You should not stop using Formoterol without talking to your doctor first.

Children
Administration of this product to children must be supervised by an adult.

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

Formoterol effects and side effects can increase if you take it with other beta-adrenergic substances (used to treat hypertension or cardiac diseases) or ephedrine (used to treat hypotension associated with anaesthesia) and anticholinergic agents (medication used to treat respiratory, intestinal diseases).

Formoterol effect can completely or partially be decreased if you simultaneously take it with beta blockers (substances used to treat hypertension, cardiac insufficiency, angina pectoris, anxiety, abnormal change in heartbeat frequency and glaucoma), including eye drops.

Formoterol may interact with monoamine oxidase inhibitors (used to treat depression). Formoterol should not be given to patients receiving this treatment or up to 14 days after discontinuation.

The simultaneous administration of antidepressants and cardiac glycosides (substances used for the treatment of cardiac insufficiency) may increase the risk of arrhythmias (abnormal changes in heartbeat frequency).

Formoterol has a bronchodilator effect that can increase in case of taking it with corticoids (long term anti-inflammatory therapy).

Formoterol has hypokalaemic effect (a decrease in potassium levels in blood that can cause weakness, cardiac arrhythmias, renal diseases and constipation). This effect can be increased if it's taken with diuretics, steroids and xanthines (Aminophylline, Theophylline). This simultaneous treatment can cause arrhythmia especially severe in patients with ischaemic heart disease. Hypokalaemia may lead to arrythmias in patients treated with digitalis glycosides.

Formoterol has a bronchodilator effect that can be increased by xanthine derivatives.

An increase of glucose in blood may occur if Formoterol is used in combination with corticosteroids.

Simultaneous treatment of Formoterol and certain type of anaesthesic medicines (halogenated hydrocarbons) may lead to high risk of arrhythmias.

Effect of Formoterol may increase in patients treated with anticholinergic drugs (used for gastrointestinal, genitourinal and respiratory disorders), corticosteroids and xanthine derivatives (used for symptoms of asthma).

Quinidine, Disopyramide, Procainamide (medicine used to treat abnormal heart rhythm), Phenothiazides (medicine used to treat some mental disorders), antihistaminics (medicine used to treat allergies), erythromycin (antibiotic used for certain airways, eyes, ears or skin infections) and antidepressants may with cause some cardiac disorders (QT interval prolongation and increased risk of ventricular arrhythmias).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Formoterol should not be used in pregnant women.

Breast-feeding
Formoterol should not be used in the breast-feeding period.

Driving and using machines
None effects have been observed.

Formoterol contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Formoterol

Always take this medicine Formoterol exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Formoterol 12 micrograms is only for inhalation use.
The recommended dose is as follows:
Adults

- *Treatment of symptoms of bronchial asthma and other chronic obstructive reversible pulmonary diseases such a couching or difficulty to breath:* Normal maintenance dose is 1 inhalation capsule (12 micrograms) twice a day, if it is necessary to relieve possible symptoms, further 1-2 capsules (Formoterol 12-24 μg) per day may be used. The maximum daily dose is 4 capsules (48 micrograms). If the extra dosage is necessary more than twice a week, consult to your doctor.
- *Prevention of induced-exercise asthma or before an unavoidable exposure to a known allergen:* the usual dose is 1 capsule (Formoterol 12 μg) 15 minutes before expected activity or exposure to the allergen. In adult patients with serious asthma, 2 capsules (Formoterol 24 μg) may be necessary.

Use in children and adolescents
Children from 6 years:
- *Treatment of symptoms of bronchial asthma without other chronic obstructive pulmonary diseases:* normal maintenance dose is 1 inhalation capsule (Formoterol 12 μg) twice a day.

If it is necessary to relieve possible symptoms, a further 1-2 capsules per day may be used. The maximum daily dose is 4 capsules (48 micrograms).
If the extra dosage is necessary more than twice a week, the doctor should be consulted.

- *Prevention of asthma as a result of inhales agents* or: 1 inhalation capsule (Formoterol 12 μg) are inhaled 15 minutes before expected activity or exposure to the allergen.

Formoterol 12 micrograms should not be used in children under 6 years old.

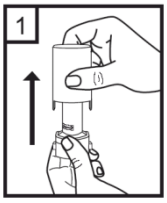
Renal and hepatic impairment
There is no theoretical reason to suggest that the Formoterol dosage requires adjustment in patients with renal or hepatic impairment, however no clinical data have been generated to support its use in these groups.

If you have the impression that the effect of Formoterol is too strong or too weak, talk to your doctor or pharmacist.

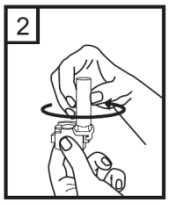
Your doctor or pharmacist should instruct you in the use of the inhaler.
The capsules should remain in the blister pack until use.

Instructions for use of the inhaler:

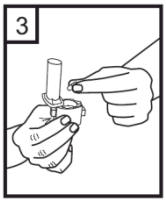
1. Pull off the cap.



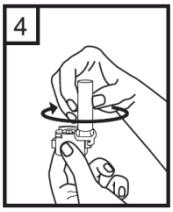
2. Hold the base of the inhaler firmly and turn the mouthpiece in the direction of the arrow to open.



3. Place one capsule in the capsule-shaped compartment in the base of the inhaler. It is important that you remove the capsule from the blister pack only immediately before you use it.

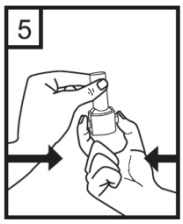


4. Twist the mouthpiece to the closed position.



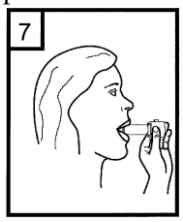
5. Keeping the inhaler upright, firmly squeeze the two buttons once only. This will pierce the capsule. Release the buttons.
   Note:
   It is possible that gelatine capsule fragment and small pieces of gelatin capsule get into mouth and throat during inhalation. Gelatine pieces are harmless and will be digested after

swallowing. The risk of fragmentation of gelatine capsule will be minimised if you remove the capsule from the blister pack immediately before use and squeeze the two buttons only once.



6. Breathe out fully.

7. Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips around the mouthpiece and breathe in as quickly and as deeply as you can.



8. Hold your breath for as long as you comfortably can while taking the inhaler out of your mouth. Then breathe normally. Open the inhaler to see if any powder is still in the capsule. If there is still powder in the capsule, repeat steps 6 to 8.
9. After use, tip out the empty capsule and close the mouthpiece.

Inhaler cleaning*:*
In order to remove residual powder, clean mouthpiece and capsule compartment with a dry cloth. Also a clean soft brush can be used.

If you take more Formoterol than you should
Immediately tell your doctor or go to the nearest hospital if you have nausea, vomiting, tachycardia (increased heart rhythm), tremor, headache, somnolence, palpitations, arrythmias (ventricular arrhythmias which are abnormal changes in the hearbeat frequency), metabolic acidosis (alteration caused by an excess of acidity in the blood that can cause an increase in the respiratory frequency, confusion and lethargy), hypotension, hypokalemia (a decrease in potassium levels in blood that can cause weakness, cardiac arrhytmias, renal diseases and constipation) and hyperglycaemia (an increase of glucose in blood that can cause thirst, frequent urination and tiredness), prolongation of QTc interval (altered rhythm of heart beating). Formoterol may provoke ischaemic heart disease (reduced blood supply to the heart muscle).

If you forget to take Formoterol
Do not take a double dose to make up for forgotten dose.

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

4. Possible side effects

Like all medicines, Formoterol this medicine can cause side effects, although not everybody gets them.
- Common (may affect up to 1 in 10 people) headache, palpitations and tremor.

- Uncommon (may affect up to 1 in 100 people): agitation, dizziness, anxiety, nervousness, insomnia, tachycardia (increased heart rhythm), aggravated bronchospasm (severe contraction of bronchi causing difficulty in breathing), muscle cramps, myalgia (pain in muscles), sleep disturbances, restlessness.

- Rare (may affect up to 1 in 1,000 people): hypersensitivity reactions (severe hypotension, angioedema which is swelling of extremities, abdomen, throat and other organs, bronchospasm which is contraction of bronchi causing difficulty in breathing,, exanthema which is skin eruption, urticaria, pruritus which is itching), nausea taste disturbances, oropharyngeal irritation (throat irritation), , cardiac arrhythmias (such as atrial fibrillation which usually associated to palpitations, fainting and chest pain, supraventricular tachycardia which means rapid heart rhythm and, extrasystoles which is irregular rhythm of the heart), low levels of potassium in blood.

- Very rare (may affect up to 1 in10,000 people): peripheral oedema (swelling of feet, hands and ankles), hyperglycaemia (increase of glucose in blood that can cause thirst, frequent urination and tiredness), angina pectoris (severe constricting pain or sensation of pressure in the chest), prolongation of QTc interval (change in the heartbeat frequency), fluctuating blood pressure, paradoxical bronchospasm (constriction of airways after treatment with bronchodilator), high levels of potassium in blood.

It can also occur an increase in blood in levels of insulin, free fatty acids, glycerol and ketone bodies.

Some of these effects can spontaneously disappear; tell your doctor if they persist or if they are highly troublesome.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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
HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FORMOTEROL

Keep this medicine out of the sight and reach of children.

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

Do not store above 25ºC.

Store in original blister in order to protect from moisture.

By medical prescription.

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 contains

- The active substance is Formoterol Fumarate. Each capsule contains 12 micrograms Formoterol Fumarate (as dihydrate).
- The other ingredient is Lactose Monohydrate. The capsule contains Gelatin.

What Formoterol looks like and contents of the pack

Formoterol inhalation powder, hard capsule are transparent capsules containing white powder.
Formoterol is supplied in blister as packages containing 1 inhaler + 10, 20, 30, 50, 56, 60, 100, 120, 180 or 200 capsules; 2 inhalers + 100 capsules; 4 inhalers + 200 capsules; 50 inhalers + 500 capsules; and 50 or 60 capsules without inhaler.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Laboratorios Liconsa, S.A.
Gran Vía Carlos III, 98, 7o
08028 Barcelona, Spain

Manufacturer:
Laboratorios Liconsa, S.A.
Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo
E-19200 Azuqueca de Henares (Guadalajara), SPAIN

This leaflet was last revised in {date}.
Detailed information on this medicine is available on the web site of the Irish Medicines Board: http://www.imb.ie.