

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Elcoterol 12 microgram powder for inhalation, hard capsule

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

What is in this leaflet

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

1. What Elcoterol is and what it is used for

Elcoterol contains a medicine called formoterol. This belongs to a group of medicines called ‘long-acting beta-agonists’ or ‘bronchodilators’

It works by relaxing the muscles in your airways. This helps you to breathe more easily. It starts to work within 1 to 3 minutes and the effects last up to 12 hours.

Your doctor has prescribed this medicine to treat your asthma or chronic obstructive pulmonary disease (COPD)

Asthma

For asthma, your doctor will prescribe two asthma inhalers: Elcoterol and a separate ‘corticosteroid’ inhaler. These should be used together.

- Elcoterol is used to help prevent asthma symptoms from happening.
- Some people also use Elcoterol when they need extra doses for relief of asthma symptoms, to make it easier to breathe again.
- Elcoterol can also be used before exercise to prevent asthma symptoms caused by exercise.

Chronic obstructive pulmonary disease (COPD)

Elcoterol can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

2. What you need to know before you use Elcoterol

Do not use Elcoterol

- If you are allergic to formoterol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Elcoterol

Before you use Elcoterol, tell your doctor or pharmacist if:

- you are diabetic. You may need some additional blood sugar tests while you are using Elcoterol
- you have high blood pressure or you have ever had a heart problem.
- you have problems with your thyroid gland.
- you have low levels of potassium in your blood. Your doctor may take blood samples to check the levels of potassium in your blood.
- you have severe liver problems such as liver cirrhosis.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Elcoterol .

Children

Do not give this medicine to children below 6 years because there is insufficient data on safety and efficacy in this age group.

Other medicines and Elcoterol

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

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

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).
- Medicines for a fast or uneven heart beat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as ‘water tablets’ (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma.
- Erythromycin (used to treat infections).
- Anti-histamines (such as terfenadine).
- Other substances that dilates the airways (bronchodilators, such as salbutamol).
- Ephedrine (used to treat asthma or as a decongestant).
- Tricyclic anti-depressants (such as amitriptyline).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Elcoterol.

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

The addition of anticholinergics (such as tiotropium or ipratropium bromide) to the treatment with Elcoterol , can help to open your airways even more.

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.

If you get pregnant while using this medicine, do not stop using Elcoterol but talk to your doctor immediately.

Driving and using machines

Elcoterol is not likely to affect you being able to drive or use any tools or machines.

Elcoterol contains lactose

The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

3. How to use Elcoterol

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

Do not increase the dose of Elcoterol prescribed by your doctor without talking to your doctor first.

If you are using Elcoterol regularly for asthma or COPD you should continue to use your medicine, even if you have no symptoms.

Continue using the inhaler for as long as you have been told unless you have any problems. In that case, talk to your doctor.

Elcoterol must only be used with the inhaler provided. You must not try to inhale Elcoterol capsules using another inhaler.

Do not put other types of capsules into the inhaler supplied with Elcoterol

Do not swallow the capsules. The contents of the capsule must be inhaled using the inhaler provided.

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using Elcoterol you should continue to use Elcoterol but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- your breathing is getting worse or you often wake up at night with asthma.
- you start getting chest tightness.
- you are not getting relief from your current dose.
- you need to take more than your usual dose for more than two days in a week.
- you need to use your Elcoterol more often than usual before exercise.

These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

Asthma

Elcoterol should not be used in children under 6 years of age.

Adults (18 years old and above)

- The usual dose is 1 inhalation (1 capsule), once or twice a day.
- Your doctor may increase this to 2 inhalations (2 capsules), once or twice a day.
- Some people also use Elcoterol as a 'reliever inhaler'. If you get asthma symptoms, the usual dose is 1 inhalation when they happen.
- A total daily dose of more than 4 inhalations (4 capsules) is not normally needed. This includes the inhalations that you take every day, when you get asthma symptoms and before exercise. However, your doctor may allow you to take up to 6 inhalations a day. Do not use more than 6 inhalations (6 capsules) in total in 24 hours.
- Do not take more than 3 inhalations (3 capsules) at any one time.

Children and adolescents (6 to 17 years old)

- The usual dose is 1 inhalation (1 capsule) once or twice a day.
- Some children also use Elcoterol as a 'reliever inhaler'. If your child gets asthma symptoms, the usual dose is 1 inhalation (1 capsule) when they happen.
- A total daily dose of more than 2 inhalations (2 capsules) is not normally needed. This includes the inhalations that your child takes every day, when they get asthma symptoms and before exercise. However, your doctor may allow your child to take up to 4 inhalations (4 capsules) a day. Your child should not use more than 4 inhalations (4 capsules) in total in 24 hours.
- Your child should not have more than 1 inhalation (1 capsule) at any one time.

Your doctor (or asthma nurse) will help you to manage your asthma. Once your asthma is well controlled your doctor may consider it appropriate to gradually reduce the dose of Elcoterol.

Asthma caused by exercise

If you or your child have asthma symptoms caused by exercise, your doctor may advise you or your child to use Elcoterol before exercise as well. Elcoterol should not be used in children under 6 years of age.

Adults (18 years old and above)

- The usual dose is 1 inhalation (1 capsule) before exercise.
- A total daily dose of more than 4 inhalations (4 capsules) is not normally needed. This includes the inhalations that you take every day, when you get asthma symptoms and before exercise. However, your doctor may allow you to take up to 6 inhalations (6 capsules) a day. Do not use more than 6 inhalations in total in 24 hours.
- Do not take more than 3 inhalations (3 capsules) at any one time.

Children and adolescents (6 to 17 years old)

- The usual dose is 1 inhalation (1 capsule) before exercise.
- A total daily dose of more than 2 inhalations (2 capsules) is not normally needed. This includes the inhalations that your child takes every day, when they get asthma symptoms and before exercise. However, your doctor may allow your child to take up to 4 inhalations (4 capsules) a day. Your child should not use more than 4 inhalations in total in 24 hours.
- Your child should not have more than 1 inhalation (1 capsule) at any one time.

Chronic obstructive pulmonary disease (COPD)

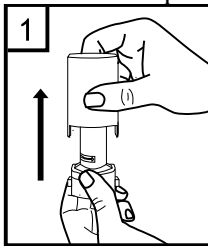
- Only to be used by adults (aged 18 years and above).
- The usual dose is 1 inhalation (1 capsule) once or twice a day.

- Your doctor may advise you to take extra doses for relief of your COPD symptoms.
- You should not have more than 4 inhalations (4 capsules) a day.
- Do not take more than 2 inhalations (2 capsules) at any one time.

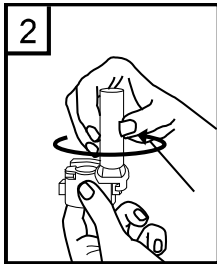
How to use the capsules with the inhaler device

A child should be shown how to use the inhaler correctly and should only use it with the help of an adult.

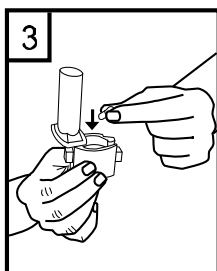
1. Pull off the cap.



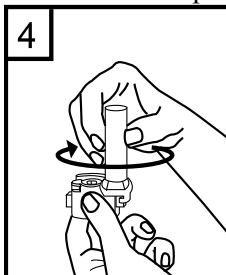
2. Hold the base of the inhaler firmly and turn the mouthpiece in the direction of the arrow to open.



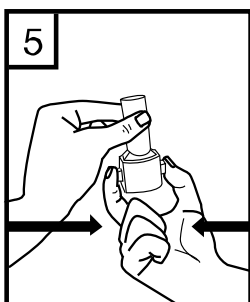
3. Take one capsule from the pack. Place it in the capsule-shaped compartment at the base of the inhaler. It is important that you only remove the capsule from the pack immediately before use.



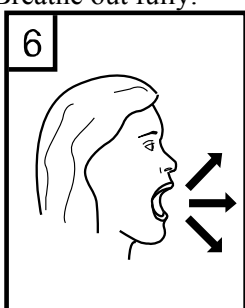
4. Twist the mouthpiece to the closed position until it clicks.



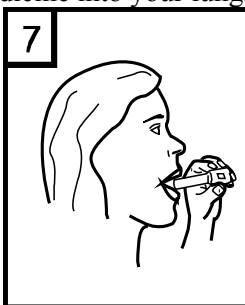
5. Keeping the inhaler upright, firmly squeeze the two buttons once only. This will pierce the capsule. Release the buttons. Although the capsule is now pierced, the powder will not be released until you inhale it.



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. As you breathe in, you will inhale the medicine into your lungs.



You should hear the capsule spinning in the inhaler. If you do not hear this whirring noise, the capsule may be stuck in the compartment. If this occurs, open the inhaler and loosen the capsule by prising it out of the compartment. Do not try to loosen the capsule by repeatedly pressing the buttons.

8. If you have heard the whirring noise, 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.

10. Replace the cap.

Cleaning your inhaler

If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a dry cloth or a clean soft brush. Do not use water or liquids.

If you use more Elcoterol than you should

If you use more Elcoterol than you should, contact your doctor or pharmacist for advice immediately. The following effects may happen: trembling, headache or a rapid heartbeat.

If you forget to use Elcoterol

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Elcoterol

Do not stop using Elcoterol without talking to your doctor.

If you have any further questions on using your inhaler device, ask your doctor, or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens to you, stop using Elcoterol and talk to your doctor immediately:

- Bronchospasm (tightening of the muscles in the airways which causes sudden wheezing) after inhaling your medicine. This happens very rarely, affecting less than 1 in 10,000 people.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use Elcoterol.
- Headache.

Uncommon (may affect up to 1 in 100 people)

- Feeling restless or agitated.
- Disturbed sleep.
- Fast heart beat.
- Muscle cramps.

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

- Uneven heart beat.
- Nausea (feeling sick).
- Low level of potassium in your blood.
- Allergic reactions such as rash, itching and bronchospasm.

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

- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.
- Feeling dizzy.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Elcoterol

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

Blister pack: Do not store above 30 °C and store in the original package in order to protect from moisture.

Bottle pack: Shelf life after first opening of the bottle is 1 month.

Store in the original package in order to protect from moisture.

This medicinal product does not require any special temperature storage conditions

Do not take the capsules out of the pack until you need them.

Do not use Elcoterol after the expiry date which is stated on the carton, and bottle or blister after EXP. The expiry date refers to the last day of that month.

If your doctor tells you to stop using Elcoterol, please take any unused capsules back to your pharmacist to be destroyed.

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 Elcoterol contains

The active substance is formoterol fumarate dihydrate. Each capsule contains 12 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (ex actuator) of 10 microgram of formoterol fumarate dihydrate.

The other excipient is lactose monohydrate, which contains milk proteins.

What Elcoterol looks like and contents of the pack

The capsules are supplied in blisters of 10, 30, 60, 120 or 180 capsules + 1 inhaler, and in HDPE bottles of 60, 120 or 180 capsules + 1 inhaler.

Not all pack sizes may be marketed.

Inhaler CE

The device conforms with Directive 93/42/EEC

Marketing Authorisation Holder

{To be completed nationally}

Manufacturer

{To be completed nationally}

Elcoterol is authorized in the Member States of the EEA under the following names:

Sweden Elcoterol 12 microgram powder for inhalation, hard capsule

France Formoterol Zentiva 12 microgrammes/heure, poudre pour inhalation, en gélule

This leaflet was last revised in 2016-05-26