

Summary Public Assessment Report

Elcoterol (formoterol fumarate dihydrate)

SE/H/1353/01/DC

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(formoterol fumarate dihydrate)

Powder for inhalation, hard capsule; 12 microgram

This is a summary of the public assessment report (PAR) for Elcoterol. It explains how Elcoterol was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Elcoterol.

For practical information about using Elcoterol, patients should read the package leaflet or contact their doctor or pharmacist.

What is Elcoterol and what is it used for?

Elcoterol is a 'hybrid generic medicine'. This means that it is similar to a reference medicine containing the same active substance, but is given by another inhaler.

The company has provided additional own data to demonstrate the safety and efficacy of Elcoterol regarding this difference from the reference medicine.

The reference medicine for Elcoterol is Foradil.

Elcoterol is used to treat 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.

How does Elcoterol work?

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.

How is Elcoterol used?

The pharmaceutical form of Elcoterol is powder for inhalation, hard capsule for inhalation.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Elcoterol have been shown in studies?

Because Elcoterol is a hybrid application and is considered to be therapeutically equivalent, to the reference product Foradil, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Elcoterol?

For the full list of all side effects reported with Elcoterol, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Elcoterol approved?

This medicine is similar to a reference medicine containing the same active substance, but is given by another inhaler. The company has provided additional own data to demonstrate the safety and efficacy of Elcoterol regarding this difference from the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Elcoterol's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Elcoterol?

A risk management plan has been developed to ensure that Elcoterol is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Elcoterol, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Elcoterol

The marketing authorisation for Elcoterol was granted on 2014-12-12 in Sweden.

The full PAR for Elcoterol can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Elcoterol, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2014-12.