LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fenorol, 12 mikrogram, Inhalation powder, hard Capsule
(formoterol fumarate dehydrate)

SE/H/1364/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Fenorol

(formoterol fumarate dihydrate)

Inhalation powder, hard capsule, 12 micrograms

This is a summary of the public assessment report (PAR) for Fenorol. It explains how Fenorol 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 Fenorol.

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

What is Fenorol and what is it used for?

Fenorol is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' already authorized in the European Union (EU) called Foradil. Foradil was first authorized in SE during 1996; however the product was subsequently withdrawn from the Swedish market during 2013. Fenorol is indicated, as add on therapy to maintenance treatment with inhaled corticosteroids, for the long-term symptomatic treatment of persistent, moderate to severe asthma in patients requiring regular bronchodilator therapy when adequate treatment with corticosteroids is not sufficient.

How does Fenorol work?

Fenorol 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 Fenorol used?

The pharmaceutical form of Fenorol is Inhalation powder, hard capsule for for inhalation use.

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 Fenorol have been shown in studies?

Because Fenorol 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 Fenorol?

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

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

Why is Fenorol approved?

This medicine is similar to a reference medicine containing the same active substance. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Fenorol'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 Fenorol?

A risk management plan has been developed to ensure that Fenorol 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 Fenorol, 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 Fenorol

The marketing authorisation for Fenorol was granted on 2015-09-17 in Sweden.

The full PAR for Fenorol can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Fenorol, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2015-09.