LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Etrilect
(bromhexine hydrochloride and ephedrine hydrochloride)

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Summary Public Assessment Report

Etrilect

(bromhexine hydrochloride and ephedrine hydrochloride)

oral solution; 0.5 mg/ml + 1 mg/ml

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

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

What is Etrilect and what is it used for?

Etrilect is a ‘generic medicine’. This means that Etrilect is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Mollipect.

Etrilect is used to treat cough with viscous mucus when there is a simultaneous need for a bronchodilator.

How does Etrilect work?

Etrilect contains bromhexine and ephedrine. Bromhexine is thought to thin the mucus in the airways. This may facilitate the expectoration of mucus. Ephedrine dilates the airways and acts to reduce mucous membrane swelling.

How is Etrilect used?

The pharmaceutical form of Etrilect is oral solution.

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 Etrilect have been shown in studies?

Because Etrilect is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Mollipect. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Etrilect?

Because Etrilect is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Etrilect approved?

It was concluded that, in accordance with EU requirements, Etrilect has been shown to have comparable quality and to be bioequivalent to the reference medicine Mollipect. Therefore, the Medical Products Agency in Sweden decided that, as for Mollipect, the benefits are greater than its risks and recommended that it can be approved for use.

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

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

The marketing authorisation for Etrilect was granted on 2017-08-11 in Sweden.

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

This summary was last updated in 2017-08.