LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bupropion Bluefish
(bupropion hydrochloride, bupropion)

SE/H/2013/01/DC

This module reflects the scientific discussion for the approval of Bupropion Bluefish. The Summary Public Assessment Report was written in March 2019 by the previous RMS NL after initial procedure NL/H/4373/001/DC and is attached at the end of this document. RMS transfer from NL to SE was completed in September 2019.

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.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Bupropionhydrochloride Bluefish 300 mg, modified-release tablets

(bupropion hydrochloride)

NL/H/4373/001/DC

Date: 7 March 2019

Summary Public Assessment Report

Generics

Bupropionhydrochloride Bluefish 300 mg, modified-release tablets
Active substance: bupropion hydrochloride

This is a summary of the public assessment report (PAR) for Bupropionhydrochloride Bluefish. It explains how this medicine 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 Bupropionhydrochloride Bluefish.

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

What is Bupropionhydrochloride Bluefish and what is it used for?
Bupropionhydrochloride Bluefish is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Elontril 300 mg modified-release tablets. Elontril is also registered under the trade names Wellbutrin XR and Bupropion-hydrochloride GSK.

This medicine is used to treat depression.

How does this medicine work?
The active substance bupropion is an antidepressant. It regulates the amount of noradrenaline (norepinephrine) and dopamine in the brain. These chemicals are naturally produced in the human body and play a role in our mood and emotions. Bupropion can improve a patient's mood. It may take two to four weeks for this medicine to have any noticeable effect.

How is this medicine used?
The pharmaceutical form of Bupropionhydrochloride Bluefish is a modified-release tablet and the route of administration is oral. The medicine can only be obtained with a prescription.

The tablet is covered by a shell that slowly releases the active substance inside the body. The tablets must not be chewed, crushed or split as this could lead to overdose, because the medicine will release too quickly. This increases the possibility of side effects, including fits.

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

How has this medicine been studied?
Because Bupropionhydrochloride Bluefish 300 mg, modified-release tablets is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Elontril. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Bupropionhydrochloride Bluefish 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 all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Elontril, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Bupropionhydrochloride Bluefish, 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 this medicine
In the Netherlands, the marketing authorisation for Bupropionhydrochloride Bluefish 300 mg, modified-release tablets was granted on 2 April 2019.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human.
For more information about treatment with Bupropionhydrochloride Bluefish, read the package leaflet (http://mri.cts-mrp.eu/Human/Product/Details/54531) or contact your doctor or pharmacist.

This summary was last updated in April 2019.