LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bupropion Orion
(bupropion hydrochloride)

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Summary Public Assessment Report

Bupropion Orion
(bupropion hydrochloride)

Modified-release tablet; 150 mg and 300 mg

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

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

What is Bupropion Orion and what is it used for?

Bupropion Orion is a 'generic medicine'. This means that Bupropion Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Voxra.

Bupropion Orion is a medicine prescribed by a doctor to treat depression.

How does Bupropion Orion work?

Bupropion Orion is a medicine prescribed by a doctor to treat depression. It's thought to interact with chemicals in the brain called noradrenaline and dopamine, which are linked with depression.

How is Bupropion Orion used?

The pharmaceutical form of Bupropion Orion is modified-release tablet for oral 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 Bupropion Orion have been shown in studies?

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

What are the possible side effects of Bupropion Orion?

Because Bupropion Orion 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 Bupropion Orion approved?

It was concluded that, in accordance with EU requirements, Bupropion Orion has been shown to have comparable quality and to be bioequivalent to the reference medicine Voxra. Therefore, the Medical Products Agency in Sweden decided that, as for Voxra, 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 Bupropion Orion?

A risk management plan has been developed to ensure that Bupropion Orion 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 Bupropion Orion, 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 Bupropion Orion

The marketing authorisation for Bupropion Orion was granted on 2015-07-16 in Sweden.

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

This summary was last updated in 2015-07.