LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Etoricoxib Orion
# (etoricoxib)

# SE/H/1554/01-04/DC

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# Summary Public Assessment Report

Etoricoxib Orion

(etoricoxib)

Film-coated tablet 30 mg, 60 mg, 90 mg, and 120 mg

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

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

## What is Etoricoxib Orion and what is it used for?

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

Etoricoxib Orion helps to reduce the pain and swelling (inflammation) in the joints and muscles of people 16 years of age and older with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout.

Etoricoxib Orion is also used for the short term treatment of moderate pain after dental surgery in people 16 years of age and older.

## How does Etoricoxib Orion work?

Etoricoxib Orion contains the active substance etoricoxib. Etoricoxib Orion is one of a group of medicines called selective COX-2 inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

## How is Etoricoxib Orion used?

The pharmaceutical form of Etoricoxib Orion is film-coated 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 Etoricoxib Orion have been shown in studies?

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

## What are the possible side effects of Etoricoxib Orion?

Because Etoricoxib 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 Etoricoxib Orion approved?

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

A risk management plan has been developed to ensure that Etoricoxib 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 Etoricoxib 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 Etoricoxib Orion

The marketing authorisation for Etoricoxib Orion was granted on 2016-12-02 in Sweden.

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

This summary was last updated in 2016-12.