

Summary Public Assessment Report

Naproxen Apofri, Naproxen Evolan (naproxen)

SE/H/2021/01-02/MR

Summary Public Assessment Report

Naproxen Apofri, 250 mg
Naproxen Evolan 500 mg
(called Naproxen Apofri/Evolan below)

naproxen

Tablet

This is a summary of the public assessment report (PAR) for Naproxen Apofri/Evolan. It explains how Naproxen Apofri/Evolan 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 Naproxen Apofri/Evolan.

For practical information about using Naproxen Apofri/Evolan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Naproxen Apofri/Evolan and what is it used for?

Naproxen Apofri/Evolan is a 'generic medicine'. This means that Naproxen Apofri/Evolan is similar to a 'reference medicine' already authorised in the European Union (EU) called Naprosyn.

[OTC]

Naproxen Apofri is used for short-term mild to moderate acute pain, e.g. headache, toothache, muscle and joint pain, back pain, and menstrual pain in adults and adolescents from 12 years of age.

Naproxen Apofri can also be used for acute attacks of migraine headaches in adults.

[Rx]

Naproxen Apofri/Evolan is used for rheumatic diseases, menstrual pains, acute migraine attacks and for mild to moderate acute pain.

How does Naproxen Apofri/Evolan work?

Naproxen Apofri/Evolan is an anti-inflammatory and analgesic drug. Naproxen Apofri/Evolan belongs to a group of medicine called NSAIDs (non-steroidal anti-inflammatory drugs). These work by reducing the formation of so-called prostaglandins, which cause pain and inflammation in the body.

How is Naproxen Apofri/Evolan used?

The pharmaceutical form of Naproxen Apofri/Evolan is tablets 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.

A prescription might be needed for this medicine in Sweden.

What benefits of Naproxen Apofri/Evolan have been shown in studies?

Because Naproxen Apofri/Evolan is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Naprosyn.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Naproxen Apofri/Evolan?

Because Naproxen Apofri/Evolan is a generic 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 Naproxen Apofri/Evolan approved?

It was concluded that, in accordance with EU requirements, Naproxen Apofri/Evolan has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Naprosyn. Therefore, the Medical Products Agency in Sweden decided that, as for Naprosyn 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 Naproxen Apofri/Evolan?

A risk management plan has been developed to ensure that Naproxen Apofri/Evolan 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 Naproxen Apofri/Evolan, 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 Naproxen Apofri/Evolan

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

This summary was last updated in 2021-04.