

Summary Public Assessment Report

Denephor (oxycodone hydrochloride and naloxone hydrochloride dehydrate)

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(oxycodone hydrochloride and naloxone hydrochloride dehydrate)

Prolonged-release tablet, 5 mg/2,5 mg, 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg

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

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

What is Denephor and what is it used for?

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

Denephor is used in for the treatment of severe pain, which can be adequately managed only with opioid analgesics. Naloxone is added to counteract constipation.

Denephor is also used for the second line symptomatic treatment of severe to very severe restless legs syndrome in people who can't be treated with dopamine medicines. Naloxone hydrochloride is added to counteract constipation.

How does Denephor work?

How Denephor works in pain relief

Denephor tablets contain oxycodone and naloxone as active substances. Oxycodone is responsible for the pain relieving effect of Denephor. It is a strong analgesic ("painkiller") that belongs to a group of medicines called opioids. Naloxone is intended to counteract constipation. Constipation is a typical side effect of treatment with opioid painkillers.

How Denephor works in restless legs syndrome

These tablets help to relieve the unpleasant sensations and so reduces the urge to move the limbs. Naloxone is intended to counteract from constipation. Constipation is a typical side effect of treatment with opioid painkillers.

How is Denephor used?

The pharmaceutical form of Denephor is prolonged-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 Denephor have been shown in studies?

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

What are the possible side effects of Denephor?

Because Denephor 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 Denephor approved?

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

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

The marketing authorisation for Denephor was granted on 2016-06-22 in Sweden.

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

This summary was last updated in 2016-07.