

Summary Public Assessment Report

Flucloxacillin Orion (flucloxacillin sodium)

SE/H/981/03/DC

Summary Public Assessment Report

Flucloxacillin Orion
(flucloxacillin sodium)

Film-coated tablet; 1 g

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

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

What is Flucloxacillin Orion and what is it used for?

Flucloxacillin Orion is a ‘generic medicine’. This means that Flucloxacillin Orion is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Heracillin.

Flucloxacillin Orion is used in the treatment of

- infections of the skin and soft tissues
- infections of the joints, bone and lungs (e.g. pneumonia, chronic bronchitis).

How does Flucloxacillin Orion work?

The active substance in Flucloxacillin Orion is flucloxacillin. Flucloxacillin is a penicillin (antibiotic), which prevents bacteria from building up a normal cell wall. Without functioning cell walls, bacteria die quickly. Flucloxacillin Orion is stable against an enzyme (lactamase), which is capable of breaking down ordinary penicillin.

How is Flucloxacillin Orion used?

The pharmaceutical form of Flucloxacillin 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 Flucloxacillin Orion have been shown in studies?

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

What are the possible side effects of Flucloxacillin Orion?

Because Flucloxacillin 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 Flucloxacillin Orion approved?

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

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

The marketing authorisation for Flucloxacillin Orion was granted on 2016-06-16 in Sweden.

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

This summary was last updated in 2016-06.