

# **Summary of risk management plan for Flucloxacillin Orion (Flucloxacillin sodium, monohydrate) Orion Corporation**

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This is a summary of the risk management plan (RMP) for Flucloxacillin Orion. The RMP details important risks of Flucloxacillin Orion, how these risks can be minimised, and how more information will be obtained about Flucloxacillin Orion's risks and uncertainties (missing information).

Flucloxacillin Orion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Flucloxacillin Orion should be used.

Important new concerns or changes to the current ones will be included in updates of Flucloxacillin Orion's RMP.

## **I. The medicine and what it is used for**

Flucloxacillin Orion is authorised for treatment of following bacterial infections when staphylococcal etiology is suspected or has been confirmed:

- Skin and soft tissue infections
- Bone/joint and lung infections, e.g. pneumonia, acute exacerbations of chronic bronchitis (see SmPC for the full indication).

It contains flucloxacillin as the active substance and it is taken by mouth.

## **II. Risks associated with the medicine and activities to minimise or further characterise the risks**

Important risks of Flucloxacillin Orion, together with measures to minimise such risks and the proposed studies for learning more about Flucloxacillin Orion's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment - so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

## II.A List of important risks and missing information

Important risks of Flucloxacillin Orion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of flucloxacillin. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Hypersensitivity/anaphylactic reactions</li> <li>• Hepatotoxicity</li> <li>• Pseudomembranous colitis</li> </ul>
Important potential risks	None identified
Missing information	None identified

## II.B Summary of important risks

The safety information in the Product Information is aligned to the reference medicinal product.

## II.C Post-authorisation development plan

There are no studies required for Flucloxacillin Orion.