

Part VI: Summary of the risk management plan

Summary of risk management plan for Nerbutix

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

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

I. The medicine and what it is used for

Nerbutix is authorised when staphylococcal etiology is suspected or confirmed for the treatment of

- Skin and soft tissue infections.
- Infections in bones and joints.
- Lower respiratory tract infections including pneumonia and pulmonary exacerbation in patients with cystic fibrosis.

It contains 50 mg/ml flucloxacillin as the active substance, and it is given orally.

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

Important risks of Nerbutix, together with measures to minimise such risks and the proposed studies for learning more about Nerbutix'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 Nerbutix are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Nerbutix. 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.

| Summary of safety concerns | |
|-----------------------------------|------|
| Important identified risk | None |
| Important potential risks | None |
| Missing information | None |

II.B Summary of important risks

Not applicable since no important risks have been identified for Nerbutix.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Nerbutix.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Nerbutix.