PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR ROCEPHIN (CEFTRIAXONE)

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

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

Important new concerns or changes to the current ones will be included in updates of Rocephin RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

Rocephin is authorized for bacterial meningitis, intra-abdominal infections, skin and soft tissue infections, acute otitis media, community acquired respiratory tract infections, hospital acquired pneumonia, complicated urinary tract infections and management of neutropenic patients with fever suspected to be due to bacterial infection, genital infections, gonorrhea and syphilis, bacterial endocarditis (infective endocarditis), disseminated lyme borreliosis 7 [early (stage II) and late (stage III)] in adults and children including neonates from 15 days of age, bacteremia that occurs in association with, or is suspected to be associated with, any of the infections listed earlier, bacterial endocarditis.

It contains ceftriaxone as the active substance and it is given by intramuscular route.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Rocephin, together with measures to minimize such risks and the proposed studies for learning more about Rocephin risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, 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 Rocephin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Rocephin. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B SUMMARY OF IMPORTANT RISKS

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

II.C POST-AUTHORIZATION DEVELOPMENT PLAN

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

There are no studies which are conditions of the marketing authorization or specific obligation of Rocephin.

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

There are no studies required for Rocephin.