Part VI: Summary of the risk management plan

Summary of risk management plan for Penicillin G Sodium

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

Penicillin G Sodium's Product Information gives essential information to healthcare professionals and patients on how Penicillin G Sodium should be used.

Important new concerns or changes to the current ones will be included in updates of Penicillin G Sodium's RMP.

I. The medicine and what it is used for

Penicillin G Sodium is indicated for the treatment of the following infections in adults, adolescents, children, new-born infants and pre-term infants, caused by penicillin-sensitive pathogens (see section 5.1 of the SmPC):

- skin and wound infections
- diphtheria (in addition to antitoxin)
- community acquired pneumonia
- empyema
- erysipelas
- bacterial endocarditis
- peritonitis
- meningitis
- brain abscesses
- osteomyelitis
- infections of the genital tract caused by fusobacteria

Penicillin G Sodium is also used for the treatment of the following specific infections:

- anthrax
- tetanus
- gas gangrene
- listeriosis
- pasteurellosis
- rat bite fever
- fusospirochaetosis
- actinomycosis

Furthermore, Penicillin G Sodium is also used for complications in gonorrhoea and syphilis (e.g. gonorrhoeal endocarditis or arthritis, congenital syphilis), provided that the isolate of Neisseria gonorrhea is documented to have sensitivity to penicillin. However, in uncomplicated cases, preference should be given to depot penicillins. Penicillin G Sodium is not indicated for the treat-ment of syphilis during pregnancy.

Penicillin G Sodium is also used in Lyme borreliosis from the second stage of the disease onwards (meningopolyneuritis Garin-Bujadoux-Bannwarth, acrodermatitis chronica atrophicans, Lyme arthritis, Lyme carditis) if oral penicillin therapy is no longer indicated. During pregnancy, high-dose parenteral Penicillin G Sodium administration is recommended from the second stage of Lyme disease onwards to prevent diaplacental infections.

The generally acknowledged guidelines for the appropriate use of antibacterial agents should be considered when using Penicillin G Sodium.

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

Important risks of Penicillin G Sodium, together with measures to minimise such risks and the proposed studies for learning more about Penicillin G Sodium'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 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*.

There is no need for additional risk minimization measures or additional pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Penicillin G Sodium 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 Penicillin G Sodium. 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).

For Penicillin G Sodium there was no important identified or potential risks or missing information that would warrant further evaluation as part of the pharmacovigilance plan and additional risk minimisation measures.

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

List of important risks and missing information	
Missing information	None

II.B Summary of important risks

Important identified risks

None

Important potential risks

None

Missing information

None

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 Penicillin G Sodium.

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

There are no studies required for Penicillin G Sodium.