## Part VI: Summary of the risk management plan

# Summary of risk management plan for Amorion Comp (amoxicillin/clavulanic acid)

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

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

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

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

Amorion Comp is authorised for the treatment of

• Acute bacterial sinusitis (adequately diagnosed)

• Acute otitis media

• Acute exacerbations of chronic bronchitis (adequately diagnosed)

• Community acquired pneumonia

• Cystitis

• Pyelonephritis

• Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis

• Bone and joint infections, in particular osteomyelitis.

See SmPC for the full indication. Amorion Comp contains amoxicillin and clavulanic acid as the active substances and it is given by mouth.

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

Important risks of Amorion Comp, together with measures to minimise such risks and the proposed studies for learning more about Amorion Comp'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 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 Amorion Comp 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 amoxicillin/clavulanic acid. 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

Safety concerns are adequately addressed in the product information.

## II.C Post-authorisation development plan

There are no studies required for Amorion Comp.

# Part VII: Annexes

## *Annex 1 – EudraVigilance Interface*

Not applicable.

## *Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme*

Not applicable.

## *Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan*

Not applicable.

## *Annex 4 - Specific adverse drug reaction follow-up forms*

Not applicable.

## *Annex 5 - Protocols for proposed and on-going studies in RMP part IV*

Not applicable.

## *Annex 6 - Details of proposed additional risk minimisation activities*

Not applicable.

## *Annex 7 - Other supporting data (including referenced material)*

Not applicable.

## *Annex 8 – Summary of changes to the risk management plan over time*

| **Version** | **Approval date**<br><br>**Procedure** | **Change** |
|---|---|---|
| 1.1 | Approved at the time of authorisation 12.3.2014.<br><br>National procedure. | <u>Safety concerns</u><br><br>*Important identified risks*<br>• Hypersensitivity reactions<br>• Hepatic disorders<br>• Crystalluria and renal impairment<br>• Colitis<br>• Mononucleosis<br>• Acute generalised exanthematous pustulosis (AGEP)<br>*Important potential risks*<br>• Lack of efficacy due to bacteria resistance |

| | | |
|---|---|---|
| | | • Dental surface disorders in children in association with amoxicillin<br>• Cases of oral cleft in association with maternal exposure to amoxicillin<br>• Potential interference with oral anticoagulant therapy<br>• Potential interactions with methotrexate, allopurinol, and mycophenolate |
| 2 | Submitted together with variation application | RMP transferred to new template and safety concerns removed |