6 PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

This is a summary of the risk management plan (RMP) for Cifoban,.

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

6.1 VI.I - The medicine and what it is used for

Cifoban is a solution for infusion, which contains the active substance sodium citrate. This medicine is intended to be used in adults and children of all age groups (except preterm newborn infants). Cifoban is used as anticoagulant during regional citrate anticoagulation in the following dialysis and plasma exchange therapies: continuous venovenous haemodialysis (CVVHD), continuous venovenous haemodiafiltration (CVVHDF), sustained low efficiency (daily) dialysis (SLEDD) and therapeutic plasma exchange (TPE) via membrane plasma separation.

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

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

6.2.1 VI.II.A - List of important risks and missing information

Important risks of Cifoban 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 Cifoban. 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). Table 5

Important identified risks	**none**
Important potential risks	**none**
Missing information	**none**

6.2.2 VI.II.B - Summary of important risks

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

6.2.3 VI II.C - Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligations for Cifoban.

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

There are no studies required for Cifoban,.