PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for ALBUMIN

This is a summary of the risk management plan (RMP) for HUMAN ALBUMIN BAXTER/ALBUMIN IMMUNO/BUMINATE/FLEXBUMIN (subsequently referred to as 'ALBUMIN' in this RMP summary). The RMP details important risks of ALBUMIN, how these risks can be minimised, and how more information will be obtained about ALBUMIN's risks and uncertainties (missing information).

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

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

I The medicine and what it is used for:

ALBUMIN is authorised for hypovolemia, hypoalbuminemia and cardiopulmonary bypass surgery. It contains Albumin as the active substance and it is given by the intravenous route, or it can also be diluted in an isotonic solution (e.g. 5 % glucose or 0.9 % sodium chloride).

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

Important risks of ALBUMIN, together with measures to minimise such risks and the proposed studies for learning more about ALBUMIN'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 assessmentso that immediate action

can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of ALBUMIN is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of ALBUMIN 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 ALBUMIN. 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 15. List of Important Risks and Missing Information

Important identified risks	• Hypersensitivity
Important potential risks	• Transmission of infectious agents
Missing information	• Use in children and adolescents below 18 years • Use in pregnant or lactating women

II.B Summary of Important Risks

Table 16. Important Identified Risk: Hypersensitivity

Evidence for linking the risk to the medicine	Prescribing Information, post-marketing data, medical literature.
Risk factors and risk groups	Atopic patients or patients with previous history of hypersensitivity to ALBUMIN or any other of its constituents.

Table 16. Important Identified Risk: Hypersensitivity

Risk minimisation measures	**Routine risk minimisation measures:** Section 4.3, 4.4 and 4.8 of the SmPC **Additional risk minimisation measures:** None.

Table 17. Important Potential Risk: Transmission of infectious agents

Evidence for linking the risk to the medicine	Prescribing Information, medical literature
Risk factors and risk groups	Patients with increased exposure to human blood or plasma derived products have an increased risk of viral transmission.
Risk minimisation measures	**Routine risk minimisation measures:** Section 4.4 of the SmPC **Additional risk minimisation measures:** None.

Table 18 Missing Information: Use in children and adolescents below 18 years

Risk minimisation measures	**Routine risk minimisation measures:** None. **Additional risk minimisation measures:** None.

Table 19. Missing Information: Use in pregnant or lactating women

Risk minimisation measures	**Routine risk minimisation measures:** Section 4.6 of the SmPC **Additional risk minimisation measures:** None.

II.C Post-Authorisation Development Plan

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

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

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

There are no studies required for ALBUMIN.