Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Albiomin 5% and 20% are solutions for intravenous infusion (infusion into a vein) for restoration and maintenance of circulating blood volume where there is a low blood volume and the use of a colloid, such as albumin, is required.

No data on the incidence and prevalence of clinical situations requiring the application of human albumin are available.

Human albumin preparations are used in all age groups. Patients who receive human albumin are often critically ill, attend an intensive care unit and have by their underlying diseases (clinical conditions after surgery, accidents, burn, etc.) an increased risk for even fatal outcome.

VI.2.2 Summary of treatment benefits

Albiomin 5% and 20% are considered efficacious and effective medicinal products in the indication restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated and use of colloids is appropriate.

Human albumin was developed in 1940s and is since that time successfully applied in the management of the wide range of medical and surgical conditions. Since more than 6 decades, the desired effects as well as side effects of human albumin are known. The way of manufacturing of human albumin is almost the same for a large number of producers.

Thus, the implementation of pre-clinical and clinical studies for human albumin products proving efficacy and safety could be abandoned by the individual manufacturer.

VI.2.3 Unknowns relating to treatment benefits (1 short paragraph per indication of 50 words maximum)

Human albumin preparations have been in clinical use for more than 6 decades, therefore the desired effects are well known. Human albumin is a normal constituent of the human plasma and acts like the physiological albumin. There is no evidence to suggest that efficacy would be different in certain sub-populations.

VI.2.4 Summary of safety concerns

Identified risks

Risk	What is known	Preventability
Hypersensitivity reactions including anaphylactic shock	Although most hypersensitivity reactions are mild, anaphylactic shock is a serious, potentially life-threatening ADR with rapid onset after (start of) infusion. Albiomin 5% and 20% must not be used if a patient is	Yes, by monitoring for early symptoms during infusion: Mild (non IgE-mediated/ anaphylactoid) reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Suspicion of allergic or anaphylactic type reactions

Risk	What is known	Preventability
	allergic (hypersensitive) to albumin preparations or to any of the other ingredients of Albiomin 5% and 20%. Very rarely, severe reactions such as shock may occur.	requires an immediate stop of the infusion and appropriate treatment to be started.

Potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Transmission of infective agents	When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of transmitting an infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections. There are no reports of virus infections with human albumin manufactured to European Pharmacopoeia specifications by established processes.
Hypervolaemia	Hypervolaemia, or fluid overload, describes the medical condition where there is too much fluid in the blood. To prevent hypervolaemia and its potentially life-threatening consequences such as lung edema the concentration of the albumin preparation, dosage and the infusion rate should be adjusted according to the individual circumstances and the indication.

Missing information

Risk	What is known
None	N/A

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the

medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Human Albumin 5% and for Human Albumin 20% can be found in the Paul-Ehrlich-Institut's EPAR page.

For the following safety concerns only routine risk minimisation measures are applied:

- Identified risk: Hypersensitivity reactions including anaphylactic shock
- Potential risk: Transmission of infective agents
- Potential risk: Hypervolaemia

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable

Studies which are a condition of the marketing authorisation

Not applicable

VI.2.7 Summary of changes to the Risk Management Plan over time

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
Version 01	22/01/2009	Identified risks: none Potential risks: none Missing information: none	
Version 02	31/10/2013	Identified risk: Anaphylactic reactions including anaphylactic shock Potential risk: Transmission of infective agents Potential risk: Hypervolaemia	Source: Spontaneous reports from the post-marketing database, literature, theoretical considerations Guideline on the warning on transmissible agents in summary of product characteristics (SmPCs) and package leaflets for plasma-derived medicinal products, EMA/CHMP/BWP/360642/2010 rev. 1 Guideline on core SmPC for human albumin solution EMA/CHMP/BPWP/494462/2011 rev.3

Version	Date	Safety Concerns	Comment
Version 03	01/07/2014	Identified risk: Anaphylactic reaction including anaphylactic shock corrected to "Hypersensitivity reaction including anaphylactic shock"	The previous term anaphylactic reactions was updated to hypersensitivity reactions to cover also non-IgE mediated reactions, as most of the observed reactions due to this class effect represent non-IgE mediated hypersensitivity reactions, usually mild. Further current data (safety and exposure) was updated according to new DLP with editorial changes.