Albuman 40 g/l solution for infusion

Albuman 200 g/l solution for infusion

30.1.2014, Version 1

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Albuman can be used in a wide variety of situations in which large amounts of albumin must be administered, such as ascites (abdominal dropsy) with paracentesis (abdominal fluid sampling), shock or imminent shock, failure of the kidneys, severe burns, serious infections complicated by the loss of proteins, in case of a serious shortage of albumin in the blood after surgery, transient arterial low blood pressure during haemodialysis, or as additional treatment for pre-term infants with a too high bilirubin concentration in their blood. Albumin is the most abundant protein in human blood. The main function of albumin is to stabilize the circulating blood volume. It also acts as a carrier for other proteins, hormones, enzymes, medicinal products and toxins.

VI.2.2 Summary of treatment benefits

Albuman is prescribed to critically ill patients if they are suffering from a too low circulating blood volume to restore and maintain the blood volume.

Albumin was first approved as a medicinal product by the FDA in 1942, and it was licensed in the USA in 1954. By the time albumin was included in the European definition of a medicinal product, in the early 1990's, albumin had been in clinical use for half a century. The pharmacological and physiological effects of albumin are well-established in humans, and studies in human subjects to demonstrate further safety and efficacy have not been deemed necessary with Albuman.

VI.2.3 Unknowns relating to treatment benefits

Albumin has been used to treat a variety of patients for many decades. Although no studies have been conducted in special age groups such as children, or in pregnant or lactating women, clinical experience with albumin suggests that no harmful effects on the course of pregnancy or on the unborn or the new born child are to be expected.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Acute serious allergic reaction (allergic, anaphylactic or hypersensitivity reaction)	As for all products that are made from human blood there is a small chance that a patient would have a severe allergic reaction	If a patient is known to have an allergy to Albuman, treatment should not be given.

Risk	What is known	Preventability
	after the administration of Albuman. Signs and symptoms of an allergic reaction are chest tightness, breathlessness and a low blood pressure. Until now the occurrence of an allergic reaction after treatment with Albuman has been reported only once.	If signs and symptoms of an allergic reaction occur the infusion should be stopped immediately.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Overload (Hypervolaemia)	Hypervolaemia may occur when the dosage has not been adjusted to the patient's individual requirements. At the first clinical signs of overload the infusion should be stopped immediately. Physicians are alerted to the possibility of overload by a clear description in the Summary of Product Characteristics.
Passing on infections (Infective agent transmission)	When medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. Therefore, 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 passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses and other types of infections.

Missing information

Risk	What is known
There is limited information on the use of Albuman in children, pregnant or breast feeding women.	Extensive experience with albumin in humans over decades has not revealed any effects of concern. Treatment with albumin is therefore not expected to be associated with any safety concern.

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 Albuman can be made available on request. This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

For this medicine there is no post authorisation development plan.

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

This is the first Risk Management Plan.