VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Acute renal failure (ARF) is a sudden decrease in kidney function. It is a life-threatening condition and often occurs as a complication to critical illness, including trauma or sepsis. The patients often have various underlying conditions, including liver disease / decreased liver function, multiple organ failure, bleeding tendencies and heart conditions, etc. More than 50% of ARF patients die, mostly due to their underlying condition.

In Europe it is estimated that between 1 to 6 persons out of 10.000 may experience ARF requiring treatment with dialysis.

VI.2.2 Summary of treatment benefits

No specific drugs are available for treating ARF. The main treatment option is to support the kidney function as much as possible, which is done in dialysis ("Renal replacement therapy" (RRT)). In dialysis, the patient is connected via blood tubes to a dialysis machine equipped with a filter, which functions as an "external kidney". During dialysis excess fluid and soluble substances are removed. Some of the fluid removed is replaced by dialysis fluids (so-called replacement solutions).

Various methods of dialysis are available, and one of them is continuous dialysis (Continuous Renal Replacement Therapy (CRRT), where the patient is placed on continuous dialysis for an undefined period of time.

VI.2.3 Unknowns relating to treatment benefits

In published studies from Europe, Asia and the United States, patients were aged from newborns to elderly over 75 years of age. There is no evidence to suggest that results would be any different in other patient groups.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Too much fluid in the body (Hypervolaemia)	Hypervolaemia is generally mild. It is easily corrected by adjustment of treatment.	Yes, by close monitoring of the patient's fluid balance during treatment

Risk	What is known	Preventability
Acid-base imbalances (Acid-base imbalances, incl. acidosis, alkalosis)	Acid-base imbalances are generally mild. They are easily corrected by adjustment of treatment.	Yes, by adjusting the blood flow rate and/or the solution flow rate.
Electrolyte imbalances (Electrolyte imbalances incl. hypocalcaemia, hyperkalaemia, hyperphosphataemia)	Electrolyte imbalances are generally mild and are easily corrected by adjustment of treatment.	Yes, by close monitoring of the patient's electrolyte levels, in particular calcium, potassium and phosphate
Too little fluid in the body (Hypovolaemia)	Hypovolaemia is generally mild. It is easily corrected by adjustment of treatment.	Yes, by close monitoring of the patient's fluid balance during treatment

Important potential risks

None

Important missing information

None

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 SD1 can be found in the website of your national health authority.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies are proposed.

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

As this is the first version of the RMP, no changes over time have occurred.

Major changes to the RMP over time

Version	Date	Safety Concerns	Comment
1.0	At time of marketing authorisation application	Identified risks: Fluid imbalances Acid-base imbalances Electrolyte imbalance Potential Risks: Blood loss Hypovolaemia Infection	
2.0	At time of authorisation	Identified risks: Hypervolaemia Hypovolaemia Acid-base imbalances Electrolyte imbalance Potential Risks: None	Hypervolaemia and hypovolaemia are not newly identified risk. They were described as a group (Fluid imbalances) in version 1.0 The potential risk blood loss is related with the procedure rather than with the medicinal product itself and consequently removed as potential risks of the medicinal product. The potential risk infection applies for any drug – i.e. potential for contamination - it is not a risk associated specific to the drug product itself. Consequently it has been removed as potential risks of the medicinal product.