



Water for Injections CSL Behring (Water for Injections Ph. Eur.)

**Public Summary of Risk Management Plan
(Extract from the EU Risk Management Plan
Version 1.0; 24-Oct-2018)**

Part VI: Summary of the risk management plan

Summary of Risk Management Plan for Water for Injections Ph. Eur.

This is a summary of the risk management plan (RMP) for Water for Injections CSL Behring.

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

I. The medicine and what it is used for

Water for Injections CSL Behring is authorized for use as a solvent for reconstitution of suitable medicinal products. The only ingredient is sterile water for injections. Dosage and method of administration depend on the instructions given for the medicinal products to be dissolved or diluted.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Reconstitution must be carried out under aseptic conditions to avoid contamination during preparation and infusion of the product.

No important potential or identified risks are known when Water for Injections CSL Behring is used as a solvent for reconstitution of suitable medicinal products as addressed to patients and healthcare professionals in the SmPC and package leaflet.

The authorized pack size is chosen so to ensure that the reconstituted medicine is used correctly.

The medicine's legal status – the way a medicine is supplied to the patient – is with prescription only.

II.A List of important risks and missing information

Important risks are risks that need special risk management activities to further investigate or minimize 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 the medicinal product. 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 (eg, on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	N/A
Important potential risks	N/A
Missing information	N/A

II.B Summary of important risks

No important risks are known when Water for Injections CSL Behring is used correctly as a solvent for reconstitution of suitable medicinal products as addressed to patients and healthcare professionals in the SmPC and package leaflet. No information on the safety of the medicinal product is considered to be missing.

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligation of Water for Injections CSL Behring.

II.C.2 Other studies in post-authorization development plan

There are no studies required for Water for Injections CSL Behring.