Summary of risk management plan for Cyclophosphamide 500 mg and 1g powder for solution for injection or infusion.

This is a summary of the risk management plan (RMP) for Cyclophosphamide 500 mg and 1g powder for solution for injection. The RMP details important risks of Cyclophosphamide 500 mg and 1g powder for solution for injection, how these risks can be minimised, and how more information will be obtained about Cyclophosphamide's risks and uncertainties (missing information).

Cyclophosphamide 500 mg and 1g powder for solution for injection or infusion summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Cyclophosphamide's 500 mg and 1g powder for solution for injection or infusion should be used.

I. The medicine and what it is used for

Cyclophosphamide may be used alone or in combination with other chemotherapeutic agents, depending on the indication. Cyclophosphamide is indicated in the treatment of:

Chronic Lymphocytic Leukemia (CLL)

Acute Lymphocytic Leukemia (ALL)

As conditioning for a bone marrow transplantation, in the treatment of Acute Lymphoblastic Leukemia, Chronic Myelogenous Leukemia and Acute Myelogenous Leukemia, in combination with whole body irradiation or busulfan.

Hodgkin's lymphoma, Non-Hodgkin's lymphoma and Multiple Myeloma.

Metastatic ovarian, and breast, carcinoma,

Adjuvant treatment of breast carcinoma

Ewing's sarcoma

Small cell lung cancer

Advanced or metastatic neuroblastoma,

Life-threatening autoimmune diseases: severe progressive forms of lupus nephritis and Wegener's granulomatosis.

It contains Cyclophosphamide as the active substance and it is given by Intravenous (infusion or direct injection).

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

Important risks of Cyclophosphamide 500 mg and 1g powder for solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Cyclophosphamide 500 mg and 1g powder for solution for injection or infusion 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.

II.A List of important risks and missing information

Important risks of Cyclophosphamide 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 Cyclophosphamide. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Cyclophosphamide 500 mg and 1g powder for solution for injection.

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

There are no studies required for Cyclophosphamide 500 mg and 1g powder for solution for injection.