PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR METHOXSALEN

This is a summary of the risk management plan (RMP) for methoxsalen. The RMP details important risks of methoxsalen, how these risks can be minimized, and how more information will be obtained about methoxsalen's risks and uncertainties (missing information).

Methoxsalen's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals on how methoxsalen should be used.

VI.I The medicine and what it is used for

Methoxsalen is authorized for in adults for extracorporeal use in the treatment of advanced-stage cutaneous T-cell lymphoma, in patients not responding to other therapies. It contains methoxsalen as active substance and it is given during extracorporeal photophoresis treatment.

VI.II Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of METHOXSALEN MACOPHARMA®, together with measures to minimize such risks and the proposed studies for learning more about methoxsalen's risks, are outlined below.

Measures to minimize 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 (at specialized centers) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation measures.*

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed via pharmacovigilance activities including signal detection and PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities.*

If important information that may affect the safe use of methoxsalen is not yet available, it is listed under 'missing information' below.

VI.II List of important risks and missing information

Important risks of methoxsalen 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 methoxsalen. 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);

Table 4: Summary Table of Important Risks and Missing Information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Patients with hepatic and renal impairment Fertility

VI.II B Summary of important risks

Table 5: Summary of important risks

Missing information: Patients with hepatic or renal impairment	
Risk minimization measures	Routine risk minimization measures: SmPC section 4.2 and 4.4
Missing information: Fertility	
Risk minimization measures	Routine risk minimization measures: SmPC section 4.6

VI.II C Post-Authorisation Development Plan

VI.II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorization or specific obligation of METHOXSALEN MACOPHARMA®.

VI.II.C.1 Other Studies in Post-Authorisation Development Plan

There are no studies required for methoxsalen.