Part VI: Summary of the risk management plan for THIAMINE HCl STEROP (thiamine hydrochloride)

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

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

Important new concerns or changes to the current ones will be included in updates of THIAMINE HCl STEROP's RMP.

I. The medicine and what it is used for

THIAMINE HCl STEROP is indicated for the prevention and the treatment of vitamin B1 deficiencies like beriberi, deficiency related to chronic alcoholism and Wernicke-Korsakoff syndrome.
It contains thiamine hydrochloride as active substance and it is given by intramuscular and intravenous route.

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

Important risks of THIAMINE HCl STEROP, together with measures to minimise such risks are outlined below.

Reference to SmPC/ PIL sections

- SmPC section 4.4 and 4.8.
- PIL section 2 and 4

Reaction observed after repeated injections of high doses from 25mg to 100mg thiamine hydrochloride, at intervals of more than 7 days. These reactions are frequently preceded by sneeze or transient pruritus. The risk of anaphylactic shock can be reduced by a slow administration over 30 minutes.

Fast intravenous administration of 100mg thiamine hydrochloride is associated with immediate burning in the arm after injection with the IV line, lasting seconds to minutes. This reaction can be avoided by a slow administration into larger veins with higher IV fluid flow rates.

It is included the specific clinical measures healthcare professionals in SmPC or patients in PIL.

In any case, the emergency medical equipment useful for treating anaphylactic shocks must be easily available.

Legal status:
Medical prescription.

Routine risk communication (Routine reporting ICSRs)
In addition to these measures, information about adverse reactions is collected continuously and is regularly analysed, 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 THIAMINE HCl STEROP is not yet available, it is listed under "missing information".

II.A List of important risks and missing information

Important risks of THIAMINE HCl STEROP 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 THIAMINE HCl STEROP.
Potential risks are concern 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	• Anaphylactic reaction • Injection site reactions
Important potential risks	• None identified
Missing information	• None identified

II.B Summary of important risks

Anaphylactic reaction (Important identified risk)	
Evidence for linking the risk to the medicine	Anaphylaxis is a systemic reaction involving multiple organ systems. It is most frequently associated with exposure to allergens and the release of mediators from mast cells and basophils. Anaphylaxis may potentially lead to death, although this is not the usual outcome. The sudden and often unanticipated onset and the catastrophic physiological impact of anaphylaxis make proper diagnosis and appropriate treatment critical to beneficial outcomes. Since the first description of anaphylaxis by Portier and Richet over a century ago, anaphylaxis has been recognized as both a dangerous and a puzzling disease. No less confounding has been the absence of consensus on definitions and diagnostic criteria, and clear insight into underlying pathophysiologic mechanisms. Recent reports have addressed these issues by proposing diagnostic criteria, identifying key chemical mediators, and identifying key intermediates contributing to mast cell and basophil activation.
Risk factors and risk groups	Anaphylactic reactions leading to shock have been reported after thiamine hydrochloride parenteral administration. This risk increases in case of repeated doses.

Risk minimisation measures	An intradermal test dose is recommended prior to administration in patients suspected to be drug sensitive. In any case, the emergency medical equipment useful for treating anaphylactic shocks must be easily available. To reduce the risk of anaphylactic shock and reactions at the injection site, the intravenous injection must be administered slowly (in 30 minutes).
Additional pharmacovigilance activities	None
Injection site reactions (Important identified risk)	
Risk minimisation measures	Routine risk communication: reference to SmPC/ PIL sections: • SmPC section 4.4 and 4.8. • PIL section 2 and 4 It is included the specific clinical measures healthcare professionals in SmPC or patients in PIL: Reported local adverse reactions are pain and inflammation at or near the injection site and local inflammation of the vein.

Important potential risks	None
Missing information	None

II.C Post-authorisation development plan

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

None

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

There are no other studies required for THIAMINE HCl STEROP.