Part VI: Summary of the risk management plan

Summary of risk management plan for Tafamidis Meglumine Lotus (Tafamidis)

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

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

Important new concerns or changes to the current ones will be included in updates of Tafamidis Meglumine Lotus's RMP.

I. The medicine and what it is used for

Tafamidis Meglumine Lotus is authorised for the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment. It contains Tafamidis as the active substance, and it is given by oral route.

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

Important risks of Tafamidis Meglumine Lotus together with measures to minimise such risks and the proposed studies for learning more about Tafamidis Meglumine Lotus's 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.

In the case of Tafamidis Meglumine Lotus, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and 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 Tafamidis Meglumine Lotus is not yet available, it is listed under 'missing information' below>.

II.A List of important risks and missing information

Important risks of Tafamidis Meglumine Lotus 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 Tafamidis Meglumine Lotus. 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	• Hepatotoxicity • Changes in thyroid function, particularly in pregnant women • Reproductive and developmental toxicity and lactation
Missing information	• Patients with severe hepatic impairment • Safety and efficacy in patients with ATTR-PN mutations other than Val30Met

II.B Summary of important risks

Important potential risks	
Reproductive and developmental toxicity and lactation	
Risk minimisation measures	Routine risk minimisation measures: Text within sections 4.4 and 4.6 of the SmPC. Prescription only medicine Additional risk minimisation measures: HCP Guide

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 Tafamidis Meglumine Lotus.

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

There are no studies required for Applicant's Tafamidis Meglumine Lotus.