EU RISK MANAGEMENT PLAN

Glatiramer acetate (Copaxone®)

RMP Version to Be Assessed as Part of This Application	
RMP Version Number	8.0
Data Lock Point for This RMP	30 September 2024
Date of Final Sign off	6 December 2024
Rationale for Submitting an Updated RMP	Removal of important identified risk “Benign neoplasms of the skin and soft tissues” and associated follow-up questionnaire

QPPV Details	
QPPV Name	Iva Novak
QPPV oversight declaration:	The content of this RMP has been reviewed and approved by the marketing authorisation holder´s QPPV/deputy.
QPPV/deputy Signature	The signature is available on file.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Copaxone® (glatiramer acetate)

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

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

Important new concerns or changes to the current ones will be included in updates of Copaxone®'s RMP.

I. The medicine and what it is used for

Copaxone® is authorised for the treatment of relapsing forms of multiple sclerosis (see SmPC for the full indication).

It contains glatiramer acetate as the active substance and it is given as a subcutaneous injection.

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

Important risks of Copaxone® together with measures to minimise such risks and the proposed studies for learning more about Copaxone®'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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including 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 Copaxone® is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Copaxone® 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 Copaxone®. 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 21: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important Identified Risks	• Liver injury
Important Potential Risks	• None
Missing Information	• Safety in paediatric patients • Safety during pregnancy

II.B Summary of Important Risks

Table 22: Important Identified Risk: Liver Injury

Important Identified Risk: Liver Injury	
Evidence for linking the risk to the medicine	Abnormal liver function test was reported commonly in clinical trials. Rare cases of severe liver injury (including hepatitis with jaundice, liver failure, and in isolated cases liver transplantation) have been reported with GA in post-marketing experience.
Risk factors and risk groups	Concomitant conditions reported in post-marketing cases included excessive alcohol consumption, existing or history of liver injury and use of other potentially hepatotoxic medication.
Risk minimisation measures	*Routine risk minimisation measures* SmPC section 4.4, 4.8. PL section 2, 4. Prescription only medicine.

Table 23: Missing Information: Safety in Paediatric Patients

Missing Information: Safety in Paediatric Patients	
Risk minimisation measures	*Routine risk minimisation measures* Information regarding limited data in paediatric population, and in which paediatric subpopulation the product should not be used in SmPC section 4.2. PL section 2. Prescription only medicine.

Table 24: Missing Information: Safety During Pregnancy

Missing Information: Safety During Pregnancy	
Risk minimisation measures	*Routine risk minimisation measures* Recommendation in SmPC section 4.6. PL section 2. Prescription only medicine.

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 Copaxone®.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Copaxone®.