Risk Management Plan (RMP) Summary

for

Xeomin ®

Powder for solution for injection

Marketing Authorisation Number: 62080

Marketing Authorisation Holder: Merz Pharma (Schweiz) AG

Active Substance: Toxinum botulinicum A (150 kD)

Document version: 1.0

Document date: 27. September 2022

Based on EU RMP version 17.1

Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Xeomin ® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Xeomin ® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Merz Pharma (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Xeomin ®.

Part VI: Summary of the risk management plan

Summary of risk management plan for Bocouture

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

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

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

I. The medicine and what it is used for

Bocouture is authorised for temporary improvement in the appearance of upper facial lines (glabellar frown lines, lateral periorbital lines, horizontal forehead lines) in adults below 65 years when the severity of these lines has an important psychological impact for the patient (see SmPC for the full indication). Bocouture contains Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins, as the active substance and is given by intramuscular injection.

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

Important risks of Bocouture, together with measures to minimise such risks and the proposed studies for learning more about Bocouture'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.

II.A List of important risks and missing information

Important risks of Bocouture 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 Bocouture. 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).

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

II.B Summary of important risks

Important identified risk
None

Important missing information
None

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 Bocouture.

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

There are no studies required for Bocouture.

Summary of risk management plan for Xeomin

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

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

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

I. The medicine and what it is used for

Xeomin is authorised for the symptomatic treatment of blepharospasm and hemifacial spasm, cervical dystonia of a predominantly rotational form (spasmodic torticollis), spasticity of the upper limb in adults and chronic sialorrhea due to neurological disorders in adults. It is also indicated for the symptomatic treatment of chronic sialorrhea due to neurological disorders and/or intellectual disability in children and adolescents (see SmPC for the full indication). Xeomin contains Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins, as the active substance and is given by intramuscular injection for blepharospasm and hemifacial spasm, cervical dystonia of a predominantly rotational form (spasmodic torticollis) and spasticity of the upper limb in adults and by intraglandular injection for sialorrhea.

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

Important risks of Xeomin, together with measures to minimise such risks and the proposed studies for learning more about Xeomin'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.

II.A List of important risks and missing information

Important risks of Xeomin 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 Xeomin. 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).

Xeomin	
List of important risks and missing information	
Important identified risks	None
Important potential risks	Atrophy of the salivary gland
Missing information	None

II.B Summary of important risks

Important potential risk	
Atrophy of the salivary gland	
Evidence for linking the risk to the medicine	An observed reversible minimal acinar atrophy in the treated mandibular salivary gland was seen in some rats at 40 units/ kg. Although this is far beyond the therapeutic dosing in humans (around 24 times exceeding the maximum intended clinical dose for intraglandular injection) a potential risk in human use cannot be excluded.
Risk factors and risk groups	Patients with chronic sialorrhea due to neurological disorders.
Risk minimisation measures	Routine risk minimisation measures Xeomin: Recommendation in section 4.2 of the SmPC SmPC section 5.3 provides information about atrophy of the salivary gland Additional risk minimisation measures None

Important missing information
None

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 Xeomin.

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

There are no studies required for Xeomin.