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.