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, 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 Bocouture is not yet available, it is listed under 'missing information' below.

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**.**