

## **PART VI- Summary of the risk management plan**

This is a summary of the risk management plan (RMP) for Betolo oromucosal spray, solution. The RMP details important risks of < Product name > oromucosal spray, how these risks can be minimised, and how more information will be obtained about < Product name > oromucosal spray 's risks and uncertainties (missing information).

Betolo oromucosal spray, solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Betolo oromucosal spray, solution should be used.

Important new concerns or changes to the current ones will be included in updates of Betolo oromucosal spray, solution's RMP.

### **I. The medicine and what it is used for**

Betolo oromucosal spray, solution is authorised for local symptomatic relief of mild infections of the mouth and throat associated with pain and without fever in adults and adolescents 12 years of age and older (see SmPC for the full indication). It contains lidocaine hydrochloride, amylmetacresol and 2, 4-dichlorobenzyl alcohol as active substances and it is given by oromucosal use.

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

Important risks of Betolo oromucosal spray, solution, together with measures to minimise such risks and the proposed studies for learning more about Betolo oromucosal spray, solution '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 in PSUR's, 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 Betolo oromucosal spray, solution are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Betolo oromucosal spray, solution. 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).

| <b>List of important risks and missing information</b> |      |
|--|------|
| Important identified risks                             | None |
| Important potential risks                              | None |
| Missing information                                    | None |

### **II.B Summary of important risks**

The safety information in the proposed Product Information is aligned with the reference medicinal product.

### **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 Betolo oromucosal spray, solution.

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

There are no studies required for Betolo oromucosal spray, solution.