

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Xylometazoline hydrochloride**

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

Xylometazoline hydrochloride's SmPC and its package leaflet give essential information to healthcare professionals and patients on how xylometazoline hydrochloride should be used.

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

Xylometazoline hydrochloride is authorised for short symptomatic treatment of nasal congestion caused by rhinitis or sinusitis (see SmPC for the full indication). It contains xylometazoline as the active substance and it is given by nasal spray.

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

Important risks of xylometazoline hydrochloride, together with measures to minimize such risks and the proposed studies for learning more about xylometazoline hydrochloride risks, are outlined below.

Measures to minimize 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 minimize 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 xylometazoline hydrochloride is not yet available, it is listed under 'missing information' below.

##### **II.A List of important risks and missing information**

Important risks of xylometazoline hydrochloride are risks that need special risk management activities to further investigate or minimize 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 xylometazoline hydrochloride. 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 to 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 for xylometazoline hydrochloride.

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

There are no studies required for xylometazoline hydrochloride.