

## **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 risk	<ul style="list-style-type: none"><li>• Rebound congestion / rhinitis medicamentosa</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• Misuse</li><li>• Overdose,</li><li>• Long-term use (more than 7 days)</li></ul>
Missing information	None

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

<b>Important Identified Risk: Rebound congestion / rhinitis medicamentosa</b>	
Risk factors and risk groups	Patients using xylometazoline nasal spray longer than recommended.
Risk minimisation measures	<p><u>Routine risk communication:</u></p> <p>SmPC Section 4.4</p> <p>Patient Information Leaflet Section 2</p> <p><u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u></p> <p>SmPC Section 4.4</p> <p>“TELEVITICA contains BAC as a preservative which, especially when used for long periods of time, can cause swelling of the nasal mucosa.”</p> <p><u>Other routine risk minimisation measures beyond the Product Information:</u></p> <p>None</p>
Additional pharmacovigilance activities	None

<b>Important Potential Risk: Misuse</b>	
Risk factors and risk groups	People prone to psychoactive substances abuse.
Risk minimisation measures	<u>Routine risk communication:</u> SmPC Section 4.2, 4.4 Patient Information Leaflet Section 2 and 3
Additional pharmacovigilance activities	None

<b>Important Potential Risk: Overdose</b>	
Risk factors and risk groups	Patients who exceed the recommended daily dosage.
Risk minimisation measures	<u>Routine risk communication:</u> SmPC Section 4.4 Patient Information Leaflet Section 2 <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> SmPC Section 4.9 In case of excessive instillation of the product in the nose and paranasal sinuses, repeatedly flush the nasal cavities with warm isotonic saline solution should be performed, advising the patient not to swallow this solution. If the patient is unconscious, take care that the solution is not swallowed during the flushing maneuvers. Symptomatic treatment under medical supervision is indicated. This includes observation of the individual for several hours. In the case of severe overdose with cardiac arrest, resuscitation should continue for at least 1 hour. Patient Information Leaflet Section 3 <u>Other routine risk minimisation measures beyond the Product Information:</u> None
Additional pharmacovigilance activities	None

<b>Important Potential Risk: Long-term use (more than 7 days)</b>	
Risk factors and risk groups	Patients who exceed the maximum treatment duration recommended.
Risk minimisation measures	<u>Routine risk communication:</u>

	<p>SmPC Section 4.4</p> <p>Patient Information Leaflet Section 2</p> <p><u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u></p> <p>None</p> <p><u>Other routine risk minimisation measures beyond the Product Information:</u></p> <p>None</p>
Additional pharmacovigilance activities	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 xylometazoline.

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

There are no studies required for xylometazoline.