

Evolan Pharma AB	Risk Management Plan
Name of the medicinal product: Xylometazolin ABECE utan konserveringsmedel, 0.5 mg/ml and 1 mg/ml nasal spray, solution	Version number: 2.1

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Xylometazolin ABECE utan konserveringsmedel, 0.5 mg/ml and 1 mg/ml nasal spray, solution

This is a summary of the risk management plan (RMP) for Xylometazolin ABECE utan konserveringsmedel, 0.5 mg/ml and 1 mg/ml nasal spray, solution (hereafter referred as Xylometazoline nasal spray, solution). The RMP details important risks of Xylometazolin nasal spray, solution, how these risks can be minimised, and how more information will be obtained about Xylometazoline nasal spray, solution's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Xylometazoline nasal spray, solution is authorised for treating rhinitis, for decongestion in sinusitis and for facilitating rhinoscopy.

It contains xylometazoline hydrochloride as active substance and for nasal use only.

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

Important risks of Xylometazoline nasal spray, solution, together with measures to minimise such 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

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Important risks of Xylometazoline nasal 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 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 nasal 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.

List of important risks and missing information	
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 of Xylometazoline nasal spray, solution.

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

There are no studies required for Xylometazoline nasal spray, solution.