

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Strepfen Orange Sugar-Free 8.75 mg Lozenges:

This is a summary of the risk management plan (RMP) for Strepfen Orange Sugar-Free 8.75 mg Lozenges. The RMP details important risks of Strepfen Orange Sugar-Free 8.75 mg Lozenges, how these risks can be minimised, and how more information will be obtained about Strepfen Orange Sugar-Free 8.75 mg Lozenges' risks and uncertainties (missing information).

Strepfen Orange Sugar-Free 8.75 mg Lozenges' SmPC and its package leaflet give essential information to healthcare professionals and patients on how Strepfen Orange Sugar-Free 8.75 mg Lozenges should be used.

I. The medicine and what it is used for

Strepfen Orange Sugar-Free 8.75 mg Lozenges is authorised for the short-term symptomatic relief of sore throat in adults and children aged 12 years and over (see SmPC for the full indication). It contains flurbiprofen as the active substance and it is given by oral administration.

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

Important risks of Strepfen Orange Sugar-Free 8.75 mg Lozenges, together with measures to minimise such risks and the proposed studies for learning more about Strepfen Orange SugarFree 8.75 mg Lozenges' 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.

II.A List of important risks and missing information

Important risks of Strepfen Orange Sugar-Free 8.75 mg Lozenges 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 Strepfen Orange Sugar-Free 8.75 mg Lozenges. 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);

Identified Risks	None.
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 Strepfen Orange Sugar-Free 8.75 mg Lozenges.

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

There are no studies required for Strepfen Orange Sugar-Free 8.75 mg Lozenges.