PART VI Summary of the risk management plan

This is a summary of the risk management plan for the product Flurbiprofen 8.75 mg lozenges owned by Geiser Pharma S.L. The RMP details important risks of this product, how these risks can be minimised, and how more information will be obtained about these product´s risks and uncertainties.

Flurbiprofen 8.75 mg lozenges summary of products characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how these products should be used.

I. The medicine and what is used for

Flurbiprofen 8.75 mg lozenges contains a medicine called Flurbiprofen and belongs to a group of medicines called “non-steroidal anti-inflammatory drugs (NSAIDs)” that have analgesic, antipyretic, and anti-inflammatory properties.

Flurbiprofen 8.75 mg lozenges is used to relieve the symptoms of a sore throat, such as irritation, pain, difficulty swallowing and a sore throat in adults and adolescents from 12 years of age.

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

None of the presented risks have been considered as important and having impact on the favorable risk-benefit balance of <Product name > or warranting further evaluation as part of the pharmacovigilance plan or additional risk minimization measures.

The routine pharmacovigilance practices, such as:

- collection, monitoring, evaluation and expeditious reporting of individual cases
- monitoring and evaluation of signals
- preparation and submission of periodic safety reports,

as well as routine risk minimization measures (i.e. effective labeling) are deemed sufficient.

II.A List of important risks and missing information

Not applicable.

II.B Summary of important Risks

Summary of important risks and missing information	
Important identified risks	- None
Important potential risks	- None
Missing information	- None

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

II.C Post-authorization development plan

There are not studies required for Flurbiprofen 8.75 mg lozenges.