Part VI: Summary of the risk management plan by product

Active substance	Sodium cromoglicate
Product(s) concerned (brand name(s)):	Lecrolyn sine 40 mg / ml (PFMD) eye drops, solution Lecrolyn 40 mg / ml SD eye drops, solution Lecrolyn 40 mg / ml MD eye drops, solution Lecrolyn 20 mg / ml SD eye drops, solution Lecrolyn 20 mg / ml MD eye drops, solution
MAH/Applicant name	SANTEN OY

Data lock point for this module	22 Feb 2019
Version number of this RMP Module	2.0

Part VI: Summary of the risk management plan

VI.1 Summary of risk management plan for Lecrolyn

This summary of the RMP for Lecrolyn should be read in the context of all this information. Important new concerns or changes to the current ones will be included in updates of Lecrolyn RMP.

I. The medicine and what it is used for

Lecrolyn eye drops, solution is authorised for Treatment of allergic conjunctivitis in adults and children over 4 years. It contains sodium cromoglicate as the active substance and is administered by ocular route.

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

There are no important risks for Lecrolyn eye drops.

Routine risk minimisation methods (RMM) are in use for Lecrolyn eye drops. Such RMM can be for example:

- Specific information, such as warnings, precautions and advice on correct use in the package leaflet (PIL) and Summary of product characteristics (SmPC) addressed to patients and healthcare professionals
- Important advice on the medicines 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) can help to minimise its risks

II.A List of important risks and missing information

Not applicable.

II.B Summary of important risks

Not applicable

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable.

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

Not applicable.