13 Part VI: Summary of the risk management plan for Fluorescite (Fluorescein Sodium)

This is a summary of the risk management plan (RMP) for Fluorescein. There are no important identified risks for Fluorescite.

Fluorescein summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fluorescein should be used.

13.1 Part VI: I. The medicine and what it is used for

Fluorescein is authorised for fluorescein angiography of the ocular fundus (see SmPC for the full indication). It contains fluorescein as the active substance and it is given intravenously.

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Not applicable as there are no important identified/potential risks for Fluorescite.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks 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 the medication.

Fluorescein has no important identified/potential risks.

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

13.2.2 Part VI - II B: Summary of important risks

Not applicable as there are no important risks for Fluorescein.

13.2.3 Part VI – II C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Fluorescein.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for Fluorescein.