Summary of risk management plan for Uvesol and Eleus (Clobetasol propionate)

This is a summary of the risk management plan (RMP) for Uvesol and Eleus (Clobetasol propionate). The RMP details important risks of Uvesol and Eleus and how more information will be obtained about Uvesol and Eleus risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Uvesol and Eleus are indicated for the treatment of inflammation and pain associated with ocular surgery. They contain clobetasol propionate as the active substance and are administered by ocular route of administration.

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

Important risks of Uvesol and Eleus, together with measures to minimise such risks and the proposed studies for learning more about Uvesol and Eleus' 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 Uvesol and Eleus 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 Uvesol and Eleus. 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);

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

II.B Summary of important risks

There are no important risks associated to Uvesol and Eleus, and therefore this section is not applicable.

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 Uvesol and Eleus.

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

There are no studies required for Uvesol and Eleus.