Part VI: Summary of the risk management plan

Summary of Risk Minimisation Plan for CEQUA (ciclosporin)

This is a summary of the risk management plan (RMP) for CEQUA. The RMP details important risks of CEQUA, how these risks can be minimised, and how more information will be obtained about CEQUA's risks and uncertainties (missing information).

CEQUA's EU Summary of Product Characteristics (SPC) and its package leaflet give essential information to healthcare professionals and patients on how CEQUA should be used.

I. The medicine and what it is used for

CEQUA is authorised as a calcineurin inhibitor immunosuppressant indicated to increase tear production in adult patients with moderate-to-severe Dry Eye Disease (see Prescribing Information for the full indication). It contains ciclosporin as the active substance and it is given topically as an ophthalmic solution.

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

Important risks of CEQUA, together with measures to minimise such risks and the proposed studies for learning more about CEQUA's risks, are outlined below.

Measures to minimise the risks identified for CEQUA are:

- Specific information, such as warnings and precautions, in the package leaflet and Prescribing Information addressed to patients and healthcare professionals;
- The medicine's Prescription Only status.

Together, these measures constitute routine risk minimisation measures.

II.A List of important risks and missing information

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• Cancer of the eye or skin around the eye (periocular skin cancer, conjunctival or corneal tumor)
Missing information	• None

II.B Summary of important risks

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

II.B Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation
Not applicable – there are no studies which are conditions of the marketing authorisation or specific obligation of CEQUA.

II.C.2 Other studies in post-authorisation development plan Not applicable – there are no studies required for CEQUA.