PART VI. SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Staquis (crisaborole)

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

Staquis's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Staquis should be used.

This summary of the RMP for Staquis should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Staquis's RMP.

I. The Medicine and What It Is Used For

Staquis is authorised for topical treatment of mild to moderate atopic dermatitis (AD) in patients 2 years of age and older (see SmPC for the full indication). It contains crisaborole as the active substance and it is given by external topical application.

Further information about the evaluation of Staquis's benefits can be found in Staquis's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

https://www.ema.europa.eu/en/medicines/human/EPAR/staquis

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Staquis is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of Staquis 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 Staquis. 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).

Table 1. List of Important Risks and Missing Information

Important identified risks	None
Important potential risks	None
Missing information	Use in hepatic impaired patients

II.B. Summary of Important Risks

Table 2. Summary of Important Risks and Missing Information

Important Identified Risks: None	
Important Potential Risks: None	
Missing Information: Use in hepatic impaired patients	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.2 Additional risk minimisation measures: None

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 authorisations or specific obligation of Staquis.

II.C.2. Other Studies in Post-Authorisation Development Plan

There are no studies required for Staquis.