

Part VI: Summary of the risk management plan for Ciclesonide, 80 mcg and 160 mcg per actuation, Pressurized inhalation, Solution

This is a summary of the risk management plan (RMP) for ciclesonide, 80 mcg and 160 mcg per actuation, pressurized inhalation, solution. The RMP details important risks of ciclesonide, pressurized inhalation, solution, how these risks can be minimized, and how more information will be obtained about ciclesonide, pressurized inhalation, solution's risks and uncertainties (missing information).

Ciclesonide, pressurized inhalation, solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ciclesonide, pressurized inhalation, solution should be used.

Important new concerns or changes to the current ones will be included in updates of the ciclesonide, pressurized inhalation, solution's RMP.

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

Ciclesonide, 80 mcg and 160 mcg per actuation, pressurized inhalation, solution is authorized for:

This medicine is indicated in treatment to control persistent asthma in adults and adolescents (12 years and older).

It contains ciclesonide as an active substance and is administered via intranasal route as pressurized inhalation, solution (80 mcg and 160 mcg per actuation).

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

Important risks of ciclesonide, pressurized inhalation, solution, together with measures to minimize such risks and the proposed studies for learning more about ciclesonide, pressurized inhalation, solution's risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

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

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

Important risks of ciclesonide, pressurized inhalation, solution are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 ciclesonide, pressurized inhalation, solution. 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 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

Part VI – II.B: Summary of important risks

N/A

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

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 ciclesonide, pressurized inhalation, solution.

II.C.2. Other studies in post-authorization development plan There are no studies required for ciclesonide, pressurized inhalation, solution.