

## **Summary of risk management plan for Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution**

This is a summary of the risk management plan (RMP) for Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution. The RMP details important risks of Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution, how these risks can be minimised, and how more information will be obtained about Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution risks and uncertainties (missing information).

Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution should be used.

### **I. The medicine and what it is used for**

Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution is indicated for a treatment to control persistent asthma in adults and adolescents (12 years and older).

It contains ciclesonide as the active substance and it is taken via inhalation route.

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

Important risks of Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution, together with measures to minimise such risks and the proposed studies for learning more about Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution 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 PL 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 reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health Authority, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

#### ***II.A. List of important risks and missing information***

Important risks of Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution are risks that need special risk management activities to further investigate or minimise 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 Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised 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).

<b>List of Important Risks and Missing Information</b>	
Important identified risk(s)	<input type="checkbox"/> None
Important potential risk(s)	<input type="checkbox"/> None
Missing information	<input type="checkbox"/> None

#### ***II.B. Summary of important risk***

Not applicable, since there are no safety concerns proposed.

#### ***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 Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution.

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

There are no studies required for Ciclesonide Glenmark 80 mcg Pressurised Inhalation, Solution and Ciclesonide Glenmark 160 mcg Pressurised Inhalation, Solution.