Part VI: Summary of the Risk Management Plan

Summary of risk management plan for RYALTRIS Nasal Spray

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

RYALTRIS Nasal Spray Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how RYALTRIS Nasal Spray should be used.

I. The medicine and what it is used for

RYALTRIS Nasal Spray is authorised for the following –

Treatment of moderate to severe nasal and ocular symptoms associated with allergic rhinitis and rhino-conjunctivitis in adults and children 12 years of age and older.

It contains olopatadine hydrochloride and mometasone furoate as the active substance and it is administered via nasal route.

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

Important risks of RYALTRIS Nasal Spray, together with measures to minimise such risks and the proposed studies for learning more about RYALTRIS Nasal Spray risks are outlined below.

Measures to minimise the risks identified for medicinal products include the following:

- Specific information, such as warnings, precautions, and advice on correct use, in the SmPC and PIL addressed to patients and healthcare professionals;
- 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 PSUR assessment (if required by EURD list) 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 RYALTRIS Nasal Spray is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of RYALTRIS Nasal Spray 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 RYALTRIS Nasal Spray. 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 risk(s)	• None
Important potential risk(s)	• None
Missing information	• Use in pregnancy and lactation

II.B. Summary of important risk

Important Identified Risk – None

Important Potential Risk – None

Missing Information – Use in pregnancy and lactation	
Evidence for linking the risk to the medicine	
Risk factors and risk groups	Pregnant women and breast-feeding mothers.
Risk minimisation measures	**<u>Routine risk minimisation measures:</u>** The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.6. Fertility, pregnancy and lactation **PIL:** Section 2: What you need to know before you take Ryaltris Nasal Spray – Pregnancy and breast-feeding **<u>Pack size:</u>** Available in metered dose manual spray bottle. 1 bottle with 9 g suspension in 20 ml bottles (56 actuations), 1 bottle with 18 g suspension in 20 ml bottles (120 actuations) 1 bottle with 29 g suspension in 30 ml bottles (240 actuations). Not all pack sizes may be marketed **<u>Additional risk minimisation measures:</u>** 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 authorisation or specific obligation of RYALTRIS Nasal Spray.

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

There are no studies required for RYALTRIS Nasal Spray.