Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for LEDERCORT RX (mometasone furoate monohydrate). The RMP details important risks of LEDERCORT RX, how these risks can be minimised, and how more information will be obtained about LEDERCORT RX 's risks and uncertainties (missing information).
LEDERCORT RX ‘s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how LEDERCORT RX should be used.

I. The medicine and what it is used for

LEDERCORT RX nasal spray is indicated for use in adults and children 3 years of age and older to treat the symptoms of seasonal allergic or perennial rhinitis.

LEDERCORT RX nasal spray is indicated for the treatment of nasal polyps in adults aged 18 years and older.

It contains mometasone furoate monohydrate as the active substance.

Posology

Seasonal allergic or Perennial Rhinitis

Adults (including older patients) and children 12 years of age and older: The usual recommended dose is two actuations (50 micrograms/actuation) in each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to one actuation in each nostril (total dose 100 micrograms) may be effective for maintenance. If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of four actuations in each nostril once daily (total dose 400 micrograms).

Children between the ages of 3 and 11 years: The usual recommended dose is one actuation (50 micrograms/actuation) in each nostril once daily (total dose 100 micrograms).

Nasal Polyposis

The usual recommended starting dose for polyposis is two actuations (50 micrograms/actuation) in each nostril once daily (total daily dose of 200 micrograms). If after 5 to 6 weeks symptoms are inadequately controlled, the dose may be increased to a daily dose of two sprays in each nostril twice daily (total daily dose of 400 micrograms).

If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, the patient should be re-evaluated and treatment strategy reconsidered.

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

Important risks of LEDERCORT RX together with measures to minimise such risks and the proposed studies for learning more about LEDERCORT RX '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.

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

II.A List of important risks and missing information

Important risks of LEDERCORT RX 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 LEDERCORT RX. 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 risks	none
Important potential risks	(Class Effects) Possible Systemic and Local Class Effects of Corticosteroids. Hypersensitivity reaction. - Adrenal suppression - Hypersensitivity reactions including anaphylactic reaction - Hyperglycaemia - Eye disorders (cataracts, glaucoma, increased intraocular pressure/ocular hypertension, chorioretinal disorder) - Nasal septum perforation (Class effects) Possible systemic effects of corticosteroids at high doses may include psychological or behavioural disorders - Psychological or behavioral disorders (psychomotor hyperactivity, sleep disorder, anxiety, depression, aggression [particularly in children])
Missing information	none

II.B Summary of important risks

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

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 for LEDERCORT RX.

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

There are no studies required for LEDERCORT RX.