Part VI: Summary of the risk management plan

Summary of risk management plan for [Product name] (fluticasone propionate)

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

[Product name] summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Product name] should be used.

I. The medicine and what it is used for

[Product name] is authorised for prophylaxis and treatment of of seasonal allergic rhinitis and perennial rhinitis. Each dose contains 50 microgram fluticasone propionate.

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

Important risks of [Product name], together with measures to minimise such risks and the proposed studies for learning more about [Product name]'s risks, are outlined below.

Measures to minimise the risks identified for medicinal product are:

- 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 reactions is collected continuously and regularly analysed, including PSUR assessment 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 [Product name] 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 [Product name]. 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	• Local nasal effects including epistaxis and nasal septum perforation • Ocular events (cataract, glaucoma, raised intraocular pressure) • Potent CYP3A4 inhibitors (ritonavir)
Important potential risks	• Effects on HPA axis • Effects on growth • Psychiatric or behavioural effects (psychomotor, hyperactivity, sleep disorders, anxiety, depression and aggression) • Effects on glucose metabolism • Effects on bone density • Adverse effects from self-diagnosis (i.e. Use of intranasal fluticasone propionate for medical conditions with similar symptoms to allergic rhinitis) • Misuse/Maladministration (including overdose and off-label use in paediatric patients) • Use in pregnancy
Missing information	• None

II.B Summary of important risks

Important identified risk	
Local nasal effects including epistaxis and nasal septum perforation	SmPC section 4.8 PL section 2, 3 and 4
Ocular events (cataract, glaucoma, raised intraocular pressure)	SmPC section 4.4 and 4.8 PL section 2 and 4
Potent CYP3A4 inhibitors (ritonavir)	SmPC section 4.4 and 4.5 PL section 2
Important potential risk	
Effects on HPA axis	SmPC section 4.4, 4.8, 4.9 and 5.1 PL section 2 and 4
Effects on growth	SmPC section 4.4, 4.8 and 5.1 PL section 2 and 4
Psychiatric or behavioural effects (psychomotor, hyperactivity, sleep disorders, anxiety, depression and aggression)	SmPC section 4.4 and 4.8 PL section 2 and 4
Effects on glucose metabolism	SmPC section 4.4 and 4.8 PL section 2 and 4
Effects on bone density	SmPC section 4.4 and 4.8

	PL section 2 and 4
Adverse effects from self-diagnosis (i.e. Use of intranasal fluticasone propionate for medical conditions with similar symptoms to allergic rhinitis)	Legal status SmPC section 4.2 and 4.9 PL section 3
Use in pregnancy	SmPC section 4.6 PL section 2
Missing information	
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 [Product name].

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

There are no studies required for [Product name].