Part VI: Summary of the risk management plan for Alitretinoin Orifarm

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

Alitretinoin Orifarm's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Alitretinoin Orifarm should be used.

I. The medicine and what it is used for

Alitretinoin Orifarm is authorised for use in adults who have severe chronic hand eczema that is unresponsive to treatment with potent topical corticosteroids.
It contains alitretinoin as the active substance and it is given as soft capsules.

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

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

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish, Swedish, Norwegian and Finnish Medicines Agency.
- The medicine's is prescription only medicine and must be prescribed by a dermatologist or by physicians with experience in the use of systemic retinoids who have full understanding of the risks of systemic retinoid therapy and monitoring requirements.Together, these measures constitute *routine risk minimisation* measures.

In the case of Alitretinoin Orifarm, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, 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 Alitretinoin Orifarm 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 Alitretinoin Orifarm. 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);

Summary of safety concerns	
Important identified risks	• Pregnancy and birth defects • Hyperlipidaemia • Inflammatory bowel disease
Important potential risks	• Bone demineralisation • Neuropsychiatric disorders
Missing information	• None

II.B Summary of important risks

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

Safety concern	**Risk minimisation measures**	**Additional Pharmacovigilance activities** **Originator**
Pregnancy and birth defects	<u>Routine risk minimisation measures</u>: SmPC section 4.4, 4.6 and 4.8, 5.3 Patient leaflet sections 2 and 4 Warning on labelling (box). Warning for HCPs, pharmacists and patients respectively to prevent pregnancy and teratogenicity to occur Prescription status limited to dermatologists and physicians with experience in use of systemic retinoids.	DUS, Patient and Prescriber Survey

Safety concern	Risk minimisation measures	Additional Pharmacovigilance activities Originator
	Limiting the prescription and control to skin specialists and physicians with experience in use of systemic retinoids to prevent pregnancy and teratogenicity to occur <u>Additional risk minimisation measures</u>: Pregnancy Prevention Programme consisting of the same elements as for other retinoid medicinal products: • Doctor's guide and checklist/ acknowledgement form • Pharmacist's guide • Patient's guide/card	
Hyperlipidaemia	<u>Routine risk minimisation measures</u>: SmPC section 4.4 and 4.8 Patient leaflet sections 2 and 4 <u>Additional risk minimisation measures</u>: None	None
High cardiovascular risk patients	<u>Routine risk minimisation measures</u>: SmPC section 4.4 and 4.8 Patient leaflet sections 2 and 4 <u>Additional risk minimisation measures</u>: None	None
Bone demineralisation	<u>Routine risk minimisation measures</u>: SmPC section 4.4 and 4.8 Patient leaflet sections 2 and 4 <u>Additional risk minimisation measures</u>: None	None
Inflammatory bowel disease	<u>Routine risk minimisation measures</u>: SmPC section 4.4 and 4.8 Patient leaflet sections 2 and 4	None

Safety concern	Risk minimisation measures	Additional Pharmacovigilance activities Originator
	Additional risk minimisation measures: None	
Neuropsychiatric disorders	Routine risk minimisation measures: SmPC section 4.4 and 4.8 Patient leaflet sections 2 and 4 Additional risk minimisation measures: None	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 Alitretinoin Orifarm.

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

There are no studies required for Alitretinoin Orifarm.