VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Indication: Infected atopic dermatitis

Eczema (dermatitis) is a very common skin disease involving itching and inflammation of the skin. The disease is chronic but with phases of acute disease when the skin becomes red, swollen and with vesicles and oozing or crusting. In the less active stage of the disease, there is also reddening, thickening of the skin, scaling and hardening of the skin as well as itching. Eczema affects people of all ages, but atopic eczema is more common in children. Damage to the skin as seen in eczema increases the risk of the skin to be infected.

VI.2.2 Summary of treatment benefits

Fucicort® Lipid contains two active substances, fusidic acid and betamethasone valerate. Fucicort® Lipid combines antibacterial action of fusidic acid and anti-inflammatory and anti-itching effect of betamethasone. Fusidic acid is active against many different types of

bacteria. Fucicort® Lipid is used for the treatment of eczema when bacterial infection is confirmed or suspected. The use of combinations of fusidic acid and betamethasone valerate is well known and such combinations have been on the market for decades. The efficacy of these has been established by a number of clinical studies, supporting the proposed indications, including use in children.

VI.2.3 Unknowns relating to treatment benefits

The efficacy profile of the combination fusidic acid and betamethasone valerate has been very well established over the past decades.

Although there are no or limited clinical data from the use of betamethasone on the skin of pregnant women, the product has been used in a broad spectrum of the population (including pregnant women) and there is no evidence to suggest that there are unknowns relating to treatment benefits.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Hypothalamic-pituitary-adrenal (HPA) axis suppression	Fucicort® Lipid contains betamethasone which is included in the drug class of corticosteroids. Treatment with corticosteroids may increase the risk of a condition called adrenal suppression (HPA axis suppression) which may lead to a condition called Cushing's disease. Symptoms of Cushing's disease include upper body obesity, rounded face, increased fat around the neck, thinning arms and legs, fatigue, weakness, high blood pressure, and mood disorders.	Fucicort® Lipid is not intended for use more than 14 days at a time. It should be avoided to use Fucicort® Lipid with large amounts, occlusion or prolonged treatment.
Masking, activation or aggravation of skin infections	Fucicort® Lipid contains betamethasone which is included in the drug class of corticosteroids. Treatment with corticosteroids may mask possible symptoms of infection, or increase risk of infectious diseases, worsen existing infections or reactivate dormant infections.	The following conditions should be contraindicated: Systemic fungal infections; primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment; Skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy. If infection cannot be controlled with topical treatment, it is recommended to switch to systemic treatment.
Allergic reactions	Fucicort® Lipid contains betamethasone and fusidic acid. Fucicort® Lipid contains methyl and propyl hydroxybenzoate (E218 and E216), cetostearyl alcohol and potassium sorbate as excipients. Allergic reactions may occur due to any of	All active ingredients and excipients are listed in the SmPC and Package leaflet. Hypersensitivity to fusidic acid or betamethasone

Risk	What is known	Preventability
	the substances. The symptoms of an allergic reaction can vary from mild to severe. The common allergic reactions to Fucicort® Lipid include hives, rash, fever, or contact dermatitis.	valerate or to any of the excipients listed in the SmPC and Package leaflet should be contraindicated.
Corticosteroid induced dermal atrophy	Fucicort® Lipid contains betamethasone which is included in the drug class of corticosteroids. Topical treatment with corticosteroids may increase the risk of dermal atrophy, especially when corticosteroid is used in long period. Dermal atrophy is a condition in which the upper layer of skin gets thin.	Fucicort® Lipid is not intended for use more than 14 days at a time. It should be avoided to use Fucicort® Lipid with large amounts, occlusion or prolonged treatment.
Allergic contact dermatitis	Fucicort® Lipid contains betamethasone and fusidic acid. Fucicort® Lipid cream contains methyl and propyl hydroxybenzoate (E218 and E216), cetostearyl alcohol and potassium sorbate as excipients. Potassium sorbate and cetostearyl alcohol may cause contact dermatitis. Any other substances in Fucicort® Lipid may also cause allergic contact dermatitis. Allergic contact dermatitis is an inflammation reaction on the skin after direct skin contact with a foreign substance. Typical symptoms of allergic contact dermatitis include skin redness, itching or rash after contact with Fucicort® Lipid.	All active ingredients and excipients are listed in the SmPC and Package leaflet. Hypersensitivity to fusidic acid or betamethasone valerate or to any of the excipients listed in the SmPC and Package leaflet should be contraindicated

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Teratogenic effects	There are no or limited data from the use of betamethasone on the skin of pregnant women. Studies in animals have shown reproductive toxicity. Fucicort® Lipid should not be used during pregnancy unless the pregnant woman suffers from a serious skin disorder, where treatment with Fucicort® Lipid is necessary.

Missing information

Risk	What is known
Use during pregnancy	There are no or limited amount of data from the use of betamethasone on the skin of pregnant women. Studies in animals have shown reproductive toxicity. Fucicort® Lipid should not be used during pregnancy unless the pregnant woman suffers from a serious skin disorder, where treatment with Fucicort® Lipid is necessary.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimization measures.

No additional risk minimisation measures are deemed to be necessary for this medicinal product.

VI.2.6 Planned post authorisation development plan

No post authorisation studies are planned

VI.2.7 Summary of changes to the Risk Management Plan over time

As this is the first version this section is not applicable.