Hydrokortison CCS 1% cream and ointment
15.5.2014, version 1.1

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a public summary

Hydrokortison CCS 1% cream and Hydrokortison CCS 1% ointment are intended to be used for eczema and anogenital pruritus. Hydrokortison CCS is made to relieve the inflammation in the skin, to reduce redness, and stop the itch.

VI.2.1 Overview of disease epidemiology

Eczema

What is eczema?
There are different types of eczema. The most common type is atopic eczema. The word atopic describes people with certain allergic tendencies. Atopic eczema is an inflammatory skin condition characterised by an itchy red rash which tends to flare-up from time to time. The skin usually feels dry and sometimes the affected areas of the skin become blistered and weepy and may also be infected.

The most common areas affected are next to skin creases, such as the front of the elbows and wrists, back of the knees, and around the neck. However, any areas may be affected, the face is commonly affected in babies and adults often get hand eczema but can also have eczema on the face and neck, back and chest.

Factors that may cause flare-ups or make the symptoms worse include e.g. food allergy (most common in children), soaps, detergents, house dust mite, pet dander, stress, pregnancy, habit scratching, skin infections.

What causes atopic eczema?
The cause of eczema is unknown. Genetic factors play a part and it is more common in children where any of the parents have eczema. Atopic eczema has become more common in recent years. There are various theories for this, such as changes in climate, pollution, allergies to house dust mite or pollens, diet, infections, or early-life factors. However, there is no proven single cause. There may be a combination of factors in someone who is genetically prone to eczema, which causes the drying effect of the skin and the immune system to react and cause inflammation in the skin.

Who has atopic eczema?
About 15–20% of children and 2–10% of adults have atopic eczema. In about 80% of people with atopic eczema the symptoms appear before the age of 5 years and it is unusual with an onset of atopic eczema after the age of 20 years. About 2 in 3 children with atopic eczema grow out of it by their mid-teens.

Treatment of eczema

The purpose of the treatment for eczema is to control or ease symptoms. Emollients and steroid creams or ointments are the common treatments. Emollients are lotions, creams, ointments and bath/shower additives which prevent the skin from becoming dry. Cutaneous steroids work by reducing inflammation in the skin.

Anogenital pruritus

What is anogenital pruritus?
The anogenital area is a common location for pruritic complaints. It is an unpleasant sensation that provokes a desire to scratch. The only symptom is itching, especially at night, located in the anal and genital regions.

What causes anogenital pruritus?

In most patients there is no obvious causative factor, although multiple known specific causes exists. Overall anogenital pruritus may have the same origin as many other skin conditions but may also be due a variety of different causes such as infections, some diseases with generalised itch, haemorrhoides, foods and medicines. Acute anogenital pruritus is usually caused by infections or contact dermatitis (soaps, colognes, showers, contraceptives) or due to irritating secretions. In chronic pruritus, inflammatory dermatoses and malignancies must be ruled out. Skin conditions and infections are thought to cause over half the cases of secondary pruritus ani. However, skin findings may also be entirely absent. Although pruritus is usually benign, it can be persistent and recurrent.

Who has anogenital pruritus?

Anogenital pruritis is a common problem but the exact number of people who get anogenital pruritus is unknown. However, it does seem to be more common in men than in women. It most commonly affects people between the ages of 40-60 but it can affect children and someone of any age.

Treatment of anogenital pruritus

When treating anogenital pruritus, topic irritants and potential sensitizers must be eliminated. If a causative factor is found, this should be treated. If there is no obvious cause, cleansing and toilet habits must be addressed. It is recommended to avoid scratching and keep nails short and clean, and to change underwear daily. Sedating antihistamines may limit night time symptoms. A bland soothing ointment may be recommended to use after going to the toilet and at bedtime. Mild steroids are useful to ease symptoms and treat any possible inflammation. In some patients, psychotropic agents are required to achieve adequate sedation. Antidepressants may be required in patients refractory to treatment or with underlying psychiatric disorders.

VI.2.2 Summary of treatment benefits

Corticosteroids for cutaneous use have been used to a large extent for over 50 years to treat various inflammatory skin conditions.

There are four classes of corticosteroids depending on the strength and effect: Group I mild effect, Group II medium effect, Group III strong effect and Group IV very strong effect. Hydrocortisone belongs to Group I, corticosteroid with mild effect, and is a well-tolerated corticosteroid for cutaneous use. Hydrocortisone for cutaneous use has been on the market since 1952.

The safety profile of cutaneous applied hydrocortisone preparations has been established through over 50 years of marketing experience. The most common side effects of hydrocortisone for cutaneous use are transient, local adverse effects of the skin.

When cutaneous corticosteroids are used correctly, the benefit of the treatment is far greater than the risks.

VI.2.3 Unknowns relating to treatment benefits

None currently known.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Adrenal suppression	It is known that when corticosteroids are given as injection/infusion or by mouth, there is a risk of adrenal suppression. Even if topical corticosteroids only rarely has been associated with systemic side effects, this side effect may also appear with local use of corticosteroids if the treatment gets through the skin and into the bloodstream when used on damage skin or on large inflamed areas of the skin. However, this side effect is less likely to occur with a weak than with more potent topical corticosteroids.	Since systemic exposure to hydrocortisone is negligable this side effect is very unlikely to occur. However, when occurring with potent corticosteroids recovery is generally prompt and complete upon discontinuation of the drug.
Contact dermatitis	It is known that, although uncommon, cases of allergic contact dermatitis (hydrocortisone) can occur.	This side effect can occur, however it is uncommon. The side effect is usually not serious and recovery is generally prompt and complete upon discontinuation of the drug. In the SmPC hypersensitivity is mentioned under contraindications and contact dermatitis is classified as one type of hypersensitivity reaction.

Important potential risks

Risk	What is known
Ocular complications	Topical, inhaled, and systemic corticosteroids can induce ocular complications such as glaucoma and cataracts, especially when used chronically or at high potencies There are isolated cases reports of people developing glaucoma after long-term use of topical steroids around the eyes. Hydrokortison CCS has a weak potency and are not intended for opthalmic use and care must be taken to avoid transfer of the product to the eye.

Important missing information

Risk	What is known
None	NA

VI.2.5 Summary of additional risk minimisation measures by safety concern

Not applicable. No additional risk minimisation measures are proposed for Hydrokortison CCS 1% cream and Hydrokortison CCS 1% ointment.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable. This is the first version of the RMP.