VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Bekuval is intended for the treatment of:

Steroid responsive dermatoses such as psoriasis and seborrheic dermatitis of the hairy regions, including the scalp.

Psoriasis

Psoriasis is a common chronic skin disorder. Estimates of the prevalence (proportion of individuals in a population having this disease) of psoriasis have varied across studies. A systematic review found wide variation in the global prevalence of psoriasis. The prevalence of psoriasis in adults ranged from 0.91

to 8.5 percent, and the prevalence of the disease in children ranged from 0 to 2.1 percent. Geographic location appeared to influence the likelihood of having psoriasis; disease prevalence tended to increase with increasing distance from the equator. Furthermore, there is no clear gender predilection for psoriasis. Although psoriasis can begin at any age, the disease is less common in children than adults. There seem to be two peaks for the age of onset which differ slightly between the genders: females experience onset more frequently between the ages of 20-29 and 50-59, whereas men experience onset more frequently between the ages of 30-39 and 60-79[2].

Seborrhoeic dermatitis

Seborrheic dermatitis is a chronic, relapsing, and usually mild form of dermatitis. The usual onset occurs with puberty and then it peaks at the age of 40, but is present among older people as well. The prevalence rate of seborrheic dermatitis is 3-5% with a worldwide distribution. Dandruff, the mildest form of this dermatitis, is probably far more common and present in around 15-20% of the population[9].

The prevalence of seborrheic dermatitis is increased among individuals with HIV in whom it may be a presenting sign. The prevalence has been estimated to be around 35 percent among patients with early HIV infection[7].

VI.2.2 Summary of treatment benefits

Psoriasis

The efficacy and safety of topical calcipotriene (a synthetic form of vitamin D used in psoriasis) was compared with betamethasone valerate lotion in 42 patients with scalp psoriasis. Results showed that betamethasone valerate was as effective as calcipotriene and both treatments were well tolerated[10]. Similar results were obtained in another study, where 409 patients with psoriasis were treated with calcipotriol or betamethasone 17-valerate for 6 weeks. Both treatments were demonstrated to be effective and well tolerated[11].

Seborrhoeic dermatitis

30 patients suffering from seborrhoeic or atopic dermatitis of the scalp were treated with either hydrocortisone butyrate scalp lotion or betamethasone valerate and both therapies resulted in clearance of the lesions after four weeks of treatment.

VI.2.3 Unknowns relating to treatment benefits

There are limited data regarding the effect of betamethasone valerate on fertility and usage in pregnant women and during breastfeeding.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Hypersensitivity reactions	Betamethasone valerate or any of the excipients in Bekuval 1 mg/g cutaneous solution may cause allergic reactions.	Tell your doctor before starting treatment if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of the product. Stop using Bekuval 1 mg/g

[9] http://emedicine.medscape.com/article/1108312-overview#a6 2015-12-07
[10] Duweb GA et al., Scalp psoriasis: topical calcipotriol 50 micrograms/g/ml solution vs. betamethasone valerate 1% lotion. Int J Clin Pharmacol Res 2000, 20(3-4):68-8.
[11] Cunliffe WJ et al., Comparative study of calcipotriol (MC 903) ointment and betamethasone 17-valerate ointment in patients with psoriasis vulgaris. J Am Acad Dermatol 1992, 26(5 Pt 1):736-43.

Risk	What is known	Preventability
		cutaneous solution immediately if you develop an allergic reaction and tell your doctor. Close monitoring.
Opportunistic infections	Local infections might become worse upon treatment with Bekuval 1 mg/g cutaneous solution.	Tell your doctor if you find that the area being treated becomes infected and stop Bekuval 1 mg/g cutaneous solution treatment if the infection spreads and begin treatment for the infection. Only use an occlusive dressing over Bekuval if your doctor has told you to. If you are applying Bekuval under an occlusive dressing, make sure that the skin is cleansed before a dressing is applied to prevent infections. Do not use Bekuval on open wounds. Close monitoring.
Skin disorders including atrophy with long term use	If Bekuval 1 mg/g cutaneous solution is used in large quantities for a prolonged period or if a large area of the body is treated, the product may be absorbed through the skin and into the blood stream which can e.g. result in skin thinning.	Tell your doctor before starting treatment if you suffer from infections of the scalp. Only use Bekuval for as long as your doctor recommends and according to his instructions. Close monitoring.
Endocrine disorders /adrenal suppression	When treatment is prolonged, systemic absorption may occur that can cause Cushing's syndrome including weight gain and rounding of the face (moon face) and other symptoms. Prolonged treatment may also cause adrenocortical suppression, which means that the body produces lower levels of the hormone cortisol than normal. This may in turn result in anorexia, nausea, vomiting, abdominal pain, weakness, tiredness, asthenia, prostration, myalgia, arthralgia, weight loss, postural hypotension, somnolence and depression. Continuous treatment or use of	Do not use large quantities of Bekuval for a prolonged period. Only use Bekuval for as long as your doctor recommends. If your condition does not improve speak to your doctor. Only use an occlusive dressing over Bekuval if your doctor has told you to. Close monitoring.

Risk	What is known	Preventability
	occlusion in infants and children can also give rise to adrenocortical suppression and growth retardation.	
Rebound psoriatic relapses	Topical corticosteroids should be used with caution with psoriasis, as there have been reports of development of relapses	Do only apply Bekuval cutaneous solution as informed by your doctor. Close monitoring.
Tolerance	Topical corticosteroids should be used with caution with psoriasis, as there have been reports of development of tolerance	Do only apply Bekuval cutaneous solution as informed by your doctor. Close monitoring.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Overdose / Interaction with other drugs	If Bekuval 1 mg/g cutaneous solution is used in large quantities, for a prolonged time period or if a large area is treated, the product may be absorbed through the skin and into the blood stream and result in high levels of cortisol systemically. This in turn can result in Cushing's syndrome including weight gain and rounding of the face (moon face). Prolonged treatment may also cause adrenocortical suppression, which means that the body produces lower levels of the hormone cortisol than normal. This may in turn result in stretch marks, changes in skin colour, skin thinning, anorexia, nausea, vomiting, abdominal pain, weakness, tiredness, asthenia, prostration, myalgia, arthralgia, weight loss, postural hypotension, somnolence and depression. If Bekuval is used in large quantities and/or for a prolonged period or if a large skin area is treated the product may be absorbed through the skin and into the blood stream, which in turn might result in the occurrence of interactions with other drugs.
Eye disorders	Betamethasone valerate 1 mg/g cutaneous solution should not be used in the eyes. Care must be taken to keep the preparation away from the eyes since repeated exposure may cause cataracts and glaucoma.
Use during pregnancy	There are limited data regarding effect of Bekuval 1 mg/g, cutaneous solution in the pregnancy.

Missing information

Risk	What is known
Use in breastfeeding and effect on fertility	There are limited data regarding the safety of Bekuval 1 mg/g, cutaneous solution on fertility, pregnancy and breastfeeding.
Use in children under the age of 12	There are no data regarding the safety effect of Bekuval 1 mg/g, cutaneous solution in children

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 minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Bekuval 1 mg/g cutaneous solution can be found in the national competent authority's website once approved.

VI.2.6 Planned post authorisation development plan

Not applicable.

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

Not applicable, this is the first RMP.