VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Inflammatory skin conditions include various skin diseases, out of which atopic eczema is probably the most common.

Atopic eczema is a chronic, relapsing, inflammatory skin condition characterised by an itchy red rash that favours the skin creases such as the folds of the elbows or behind the knees.* Atopic eczema is common and the prevalence is increasing. Eczema affects 15-20% of school children

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and 2-10% of adults. The large majority (about 80%) of cases present before the age of 5 years. There is an increased prevalence in those with an affected parent.

Eczema of all types frequently becomes infected with bacteria, e.g. Staphylococcus aureus, and infection may exacerbate the eczema, making it less responsive to topical corticosteroids.

VI.2.2 Summary of treatment benefits

The product Fusidic acid/Betamethasone valerate [redacted] contains the active ingredients fusidic acid 2% (20mg/g), which belongs to a group of medicines called antibiotics, and betamethasone 0.1% (1mg/g), as betamethasone valerate, which belongs to a group of medicines called steroids. Fusidic acid/Betamethasone valerate [redacted] works by reducing swelling, itchiness and redness, and by killing the bacteria that cause the skin infection on the application site.

A number of randomized clinical trials have compared the efficacy of different topical antimicrobial/corticosteroid preparations with fusidic acid/corticosteroid preparations in infected eczema.‡ The results showed that the clinical efficacy, antibacterial activity and cosmetic acceptability of fusidic acid/corticosteroid combinations are similar to or better than those of comparator combinations. Fusidic acid/steroid combinations work quickly with observable improvement within the first week. In an infected atopic dermatitis (AD), topical treatment combining the antibiotic fusidic acid and the corticosteroid betamethasone valerate has been demonstrated to be superior to treatment with corticosteroids alone.†

Studies have shown that short-term (2 weeks) use of fusidic acid/corticosteroid combinations does not increase the development of resistance. ‡

The short-term use of a fusidic acid corticosteroid combination preparation effectively controls infection without risk of drug resistance developing.

The product should not be used for those skin conditions caused only by bacteria, e.g. boils and spots, by viruses, e.g. cold sores, and by fungi, e.g. athlete's foot. It should also not be used to treat acne rosacea or a type of dermatitis with spots around the mouth and chin.

VI.2.3 Unknowns relating to treatment benefits

There are no relevant unknowns relating to treatment benefits.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Side effects caused by betamethasone valerate (steroid)	Some side effects are known to be caused by betamethasone valerate (steroid), one of the ingredients in Fusidic acid/Betamethasone valerate [redacted]. These effects may include: • Thinning of the skin (skin atrophy) • Stretch marks (striae) • Inflammation or swelling of the hair root (folliculitis) • Changes in growth of your body hair (hypertrichosis) • Red spotty rash around the mouth or chin (perioral dermatitis) • Lightening of your skin colour • Glaucoma Adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.	Warning about these undesirable effects is given in the Package Leaflet. You should tell your doctor if any of these side effects occur. Development of these side effects is preventable by respecting the maximum duration of the treatment.
Allergic reaction (hypersensitivity) to the preparation	An allergic reaction may occur towards the product, caused by hypersensitivity to fusidic acid, betamethasone or any other component of the product. This kind of reaction can be much more severe during repeated use of the product after first allergic reaction. Signs of the allergic reaction may include difficulty breathing, face or throat swell, severe skin rash or just mild skin disorders.	Instruction not to use the product in patients with known hypersensitivity is given in the Package Leaflet. Do not use Fusidic acid/Betamethasone valerate [redacted]: • If you are allergic (hypersensitive) to fusidic acid or betamethasone valerate. • If you are allergic (hypersensitive) to any of the other ingredients in your medicine. You can find a list of these ingredients in Section 6 of this leaflet.

Risk	What is known	Preventability
		You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction: • You have difficulty breathing • Your face or throat swell • Your skin develops a severe rash.
Local skin reactions e.g. itchy rash and skin inflammation in the area where the medicine is used (contact dermatitis), allergic skin reactions	These reactions are usually mild and not serious. Their frequency is not known exactly.	These reactions are not preventable.
Additional infection by bacteria, moulds or viruses (secondary bacterial, fungal or viral infections)	Infections, which are not sensitive to the treatment with the product, may occur during the treatment. Signs of infection may not be evident, since the medicine can mask them.	This event is not preventable. Instructions in the Package Leaflet should be followed, i.e. if there is no improvement after 7 days you should stop using the cream and go back to your doctor.
Adrenal glands function impairment (adrenal suppression) during long term continuous therapy particularly in children	Adrenal glands may stop working properly during long term continuous therapy particularly in children. Signs are tiredness, depression and anxiety. These problems are more likely if the medicine is used for a long time, in large amounts or on skin folds (such as armpits or under breasts). These problems are also more likely in babies and children, since these age groups are more sensitive. They are also more likely if the skin is covered with a dressing, bandage or nappy.	This problem might be preventable by limiting duration of the treatment, careful use of a dressing or bandage. These circumstances and proper duration of the treatment must be always evaluated by a physician.
Thinning of skin (atrophic changes) after prolonged treatment	The product contains a steroid (betamethasone valerate), which may cause thinning of skin after prolonged treatment.	This problem might be preventable by limiting duration of the treatment. However, it is up to the physician in charge who must decide about the appropriate duration of the treatment.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Lack of efficacy against infection (bacterial resistance)	The medicine is used to treat bacterial infection. Bacteria can adapt and find ways to survive the effects of this product. They become 'resistant' so that the product no longer works. It is therefore necessary to evaluate the course of the treatment frequently. In case of no improvement or worsening of your skin disease after 7 days at latest you should stop using the cream and go back to your doctor.
Complications related to the eye (ocular complications)	The product contains a steroid (betamethasone valerate), which may cause high pressure in the eye (glaucoma), when it gets in the eye. Glaucoma, if not detected and not treated, may result in blindness. It is therefore necessary to avoid application of the cream in the eye.

Missing information

Risk	What is known
Use in pregnancy	Safety for use of the medicine during pregnancy has not been established. Some studies in animals have shown harmful effects. The potential risk for humans is unknown, therefore the medicine should not be used during pregnancy unless clearly 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 minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Fusidic acid/Betamethasone valerate [redacted] can be found in the competent authority's webpage once approved.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post authorisation development plan was proposed by the Applicant.

* Tidy C. Atopic Dermatitis and Eczema. Last Checked: 18/02/2011 Document ID: 1144 Version: 24 Available at: http://www.patient.co.uk/pdf/1144.pdf. Accessed on 09-Apr-2013.

[†] Larsen SF, Simonsen L, Melgaard A, et al. An efficient new formulation of fusidic acid and betamethasone 17-valerate (Fucicort Lipid cream) for treatment of clinically infected atopic dermatitis. Acta Derm Venereol 2007; 87: 62–68.

[‡] Leung D, ed. Assessing the value of fusidic acid in dermatology. Acta Derm Venereol 2008; Suppl 216: 1–39