

Literature search up to 8 February 2021



In response to our request for information, Sanofi-Aventis provided us with no documentation on its product.

- 1- Prescrire Editorial Staff "Daratumumab monotherapy in relapsed and refractory multiple myeloma. No evidence of efficacy" *Prescrire Int* 2018; **27** (190): 55.
- 2- Prescrire Editorial Staff "Pomalidomide (Imnovid®) and multiple myeloma, after failure of lenalidomide" *Prescrire Int* 2021; **30** (225): 105.
- 3- Prescrire Editorial Staff "Pomalidomide. A last-line treatment option for multiple myeloma" *Prescrire Int* 2014; **23** (154): 257-259.

4- EMA - CHMP "Public assessment report for Sarclisa. EMEA/H/C/004977/0000" 26 March 2020: 125 pages.

5- HAS - Commission de la transparence "Avis-Sarclisa" 18 November 2020: 40 pages.

6- Prescrire Editorial Staff "Daratumumab (Darzalex®) as part of first-line treatment for certain types of multiple myeloma" *Prescrire Int* 2021; **41** (226): 133.

7- European Commission "SPC-Empliciti" 17 December 2020: 23 pages.



fusidic acid + betamethasone valerate cream (DERMAFUSONE®) and infected atopic eczema

NOT ACCEPTABLE

Combination of an antibiotic, which is generally not the best choice for cutaneous application, with a potent topical corticosteroid, which is liable to exacerbate the infection.

DERMAFUSONE® - fusidic acid + betamethasone cream

- 20 mg of fusidic acid + 1 mg of betamethasone (as the valerate form) per gram of cream

■ antibiotic + potent corticosteroid

■ **Indication:** "eczematous skin rash (...) when secondary bacterial infection is confirmed or suspected", in adults and children aged 1 year or older. [French marketing authorisation through a national procedure]

For children and adults with atopic eczema, daily application of an emollient is the first-line treatment. Topical corticosteroids are useful mainly to treat flare-ups. Atopic eczema is sometimes complicated by infection, most often caused by *Staphylococcus aureus* ("golden staph"), with the development of pustules and crusting (1). The best treatment option is then topical application of mupirocin, unless there is extensive infection, in which case oral antibiotic treatment is justified (2,3).

Since mid-2020, for treatment of infected eczema in children over one year of age and in adults, a cream (Dermafusone®, Bailleul) which contains fusidic acid (an antibiotic) and betamethasone (as the valerate form, a topical corticosteroid classified as having potent activity) has been marketed in France (4). Fusidic acid and betamethasone were already available in separate proprietary products, in the form of a cream or ointment (2,5).

Fusidic acid is an antibiotic which is usually effective in treating skin infections due to *S. aureus*. However, because it is also administered orally or intravenously to treat some severe *S. aureus* infections, its use should be restricted in order to minimise the risk of emergence of resistant strains. Mupirocin, in contrast, has the advantage of being solely used topically (6).

As corticosteroids are immunosuppressants, they are liable to exacerbate infections (7). When infected skin lesions are present, it would therefore seem advisable to avoid using or to discontinue the use of a topical corticosteroid while the infection is treated with an antibiotic. In 2008, the French drug regulatory agency withdrew marketing authorisations for creams and ointments which contained an antibiotic combined with a corticosteroid, because they had no demonstrated therapeutic value (8).

The combination of fusidic acid + betamethasone exposes patients to the adverse effects of both drugs. They mainly consist of: hypersensitivity reactions, sometimes manifesting as eczema, due to fusidic acid; and various localised disorders due to the corticosteroid (telangiectasia, skin atrophy and fragility, stretch marks, infections, allergies). Topical corticosteroids also carry a risk of the systemic adverse effects of corticosteroids (hyperglycaemia, hypercortisolism, adrenal suppression, growth disorders), resulting from absorption through the skin, particularly when applied to damaged skin, over large areas, or under an occlusive dressing (1,2).

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Literature search up to 26 February 2021



In response to our request for information, Bailleul provided us with no documentation on its product.

1- Prescrire Rédaction "Eczéma atopique" Premiers Choix Prescrire, updated January 2021: 6 pages.

2- Prescrire Rédaction "Acide fusidique topique: limiter la fréquence et la durée des traitements" *Rev Prescrire* 2008; **28** (300): 744.

3- "Eczema" + "Fusidic acid". In: "Martindale The Complete Drug Reference" The Pharmaceutical Press, London. www.medicinescomplete.com accessed 15 March 2021: 17 pages.

4- ANSM "RCP-Dermafusone" 9 October 2019: 4 pages.

5- Prescrire Rédaction "Spécialités à base de dermocorticoïde non associé commercialisées en France au 5 décembre 2019" *Rev Prescrire* 2020; February 2020: 1 page.

6- Prescrire Rédaction "Impétigo. Mesures d'hygiène et souvent mupirocine cutanée" *Rev Prescrire* 2018; **38** (412): 115-121.

7- Prescrire Rédaction "Durée et arrêt d'un traitement par dermocorticoïde" *Rev Prescrire* 2020; **40** (442): 611-612.

8- Prescrire Rédaction "Antibiotiques locaux (suite): retraits et restrictions bienvenus dans les infections cutanées" *Rev Prescrire* 2009; **29** (305): 181-182.