

## Calcipotriol / betamethason foam and sticky hair

### Introduction

Calcipotriol / betamethasone foam for cutaneous use (Enstilar®) is indicated *for local treatment of psoriasis vulgaris in adults*.

Calcipotriol as synthetic vitamin D3-analogue results in inhibition of growth and induction of differentiation of keratocytes, and has an immunomodulatory effect. Betamethasone as synthetic corticosteroid inhibits T-cell activation. The combination of calcipotriol and betamethasone enhances the anti-inflammatory and growth inhibitory effects.

Calcipotriol / betamethasone foam was granted marketing authorization in the Netherlands in May 2016 [1].

Psoriasis is a common chronic skin disorder characterized by erythematous plaques with silvery scales. Psoriasis can be limitedly localised or may involve the majority of the body surface. Common locations concern the scalp, elbows, knees and back [2].

### Report

On 2 February 2017 the Netherlands Pharmacovigilance Centre Lareb received one report of sticky hair associated with the use of calcipotriol / betamethasone foam.

#### Report 233888

This non-serious spontaneous report from a specialist doctor concerns a female 61-70 years, with sticky skin and hair following administration of calcipotriol / betamethasone foam for guttate psoriasis with a latency of four days after start. The use of calcipotriol / betamethasone foam on the scalp was discontinued immediately. The hairdresser had to shave the hair of the patient and treated her for four hours with white spirit (refined petrol) to remove the greasy product. The patient largely recovered from the reaction. The remaining grease will be treated again by the hairdresser in the near future. Another cause of the reaction might have been that the patient possibly used too much calcipotriol / betamethasone. Concomitant medications were atenolol, calcitriol, macrogol / electrolytes, colecalciferol, desoximetasone, omeprazole.

### Other sources of information

#### SmPC

The Dutch SmPC of calcipotriol / betamethasone **foam** (Enstilar®) mentions change of hair color as adverse reaction with unknown frequency. The SmPC explains in a footnote that, when applying on the scalp, a temporary discolouration of the hair to a yellowish color in white or gray hair was reported. The SmPC describes no further warnings or precautions concerning the hairy scalp.

Vehicles of calcipotriol / betamethasone foam include liquid paraffin and white soft paraffin [1].

The Dutch SmPC of calcipotriol / betamethasone **cream** describes no warnings or precautions concerning the hairy scalp.

Vehicles of calcipotriol / betamethasone cream include light liquid paraffin and white soft paraffin [3].

The Dutch SmPC of calcipotriol / betamethasone **gel** (Dovobet®) also describes change of hair color as adverse reaction with unknown frequency. Also the SmPC of this gel, explains in a footnote that when applying on the scalp a temporary discolouration of the hair to a yellowish color in white or gray hair was reported. Furthermore, this SmPC describes that all affected areas of the scalp may be treated.

Vehicles of calcipotriol / betamethasone gel include liquid paraffin. White soft paraffin is not reported as excipient [4].

#### Literature

An article describing a phase II study concerning combined calcipotriene plus betamethasone dipropionate aerosol foam appliance including the scalp, does not report sticky hair as an adverse drug reaction [5].

In 2016 a review was published on calcipotriol / betamethasone dipropionate foam. This article describes that in general adherence to psoriasis treatment is challenging, for reasons including vehicle issues like greasiness, oiliness and stickiness. It is important to notice, that the authors of this publication assessed that the foam had *more* potential for patient acceptance compared to other formulations, being an alcohol-free foam with a non-skin-drying emollient vehicle [6]. The website for dermatologists in the Netherlands “Huidinfo”, reports that the gel can be applied on both the body and the hairy scalp. This is not reported for the other formulations foam and cream [7].

### Databases

The Lareb [8], Eudravigilance [9] and WHO databases [10] contained no other reports of the PT “hair disorder” associated with calcipotriol / betamethasone.

### Prescription data

Table 1. Number of patients using calcipotriol combinations\*\* in the Netherlands between 2011 and 2015 [11].

Drug	2011	2012	2013	2014	2015
Calcipotriol combinations	60,142	67,279	66,036	60,449	58,782

\*\*The number of patients using specifically calcipotriol / betamethasone in the Netherlands cannot be indicated by use of the GIP database.

### Mechanism

A possible mechanism of sticky hair when using calcipotriol / betamethasone foam, is possibly through the fatty substance white soft paraffin, which is used as vehicle of the drug.

### Discussion and conclusion

The Netherlands Pharmacovigilance Centre Lareb received one case of sticky hair after using calcipotriol / betamethasone foam (Enstilar®) in the hair on the scalp, where the hairdresser had to cut the patient’s hair. It is possible though that the foam was not used correctly and possibly too much calcipotriol / betamethasone foam (Enstilar®) was used.

The SmPC of calcipotriol / betamethasone **foam** (Enstilar®) describes discolouration as adverse drug reaction. The SmPC describes no further warnings or precautions concerning the hair on the scalp.

The SmPC of calcipotriol / betamethasone **cream** also does not describe warnings or precautions concerning the hair on the scalp. Both the foam and the cream contain white soft paraffin. It might be possible that this white soft paraffin played a role in the sticky hair of the patient after using calcipotriol / betamethasone foam (Enstilar®). The use of calcipotriol / betamethasone **gel** is advised for application on the hairy scalp by “Huidinfo”, the website of dermatologists in the Netherlands [7].

Scientific publications do not support stickiness of the hair being more severe in foam compared to other formulations, and even seem to assess that the foam has a *higher* change of patient acceptance compared to other formulations [6].

Although no other cases were reported in the Lareb, Eudravigilance or WHO databases, it is advised to evaluate whether calcipotriol / betamethasone foam and cream can be use on the hairy scalp or not, and to describe this clearly in the SmPC’s and the patient leaflets.

### References

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3. Dutch SmPC calcipotriol / betamethasone cream Sandoz Enstilar, 50 microgram/g + 0,5 mg/g, zalf. Version date: 12-5-2016. Access date: 6-4-2017. <http://db.cbg-meb.nl/IB-teksten/h116941.pdf>
4. Dutch SmPC calcipotriol / betamethasone gel Dovobet, 50 microgram/0,5 mg/g gel. Version date: 8-12-2016. Access date: 6-4-2017. <http://db.cbg-meb.nl/IB-teksten/h100401.pdf>
5. Lebwohl M., Tyring S., Bukhale M. et al. Fixed Combination Aerosol Foam Calcipotriene 0.005% (Cal) Plus Betamethasone Dipropionate 0.064% (BD) is More Efficacious than Cal or BD Aerosol Foam Alone for Psoriasis Vulgaris. A Randomized, Double-blind, Multicenter, Three-arm, Phase 2 Study. J Clin Aesthet Dermatol. 2016 Feb; 9(2): 34–41

6. Kim ES, Frampton JE. Calcipotriol/Betamethasone Dipropionate Foam: A Review in Plaque Psoriasis. *Drugs*. 2016 Oct;76(15):1485-1492
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8. Lareb database. Version date: 2017. Access date: 6-4-2017. <http://www.lareb.nl/Bijwerkingen/Zoek-op-geneesmiddel>.
9. Eudravigilance database. Version date: 2017. Access date: 6-4-2017. <http://bi.eudra.org> (access restricted).
10. WHO Global Individual Case Safety Reports database (Vigibase). Version date: 2017. Access date: 6-4-2017. <https://tools.who-umc.org/webroot/> (access restricted).
11. GIP database. Version date: 2017. Access date: 6-4-2017. <https://www.gipatabank.nl/>

*This overview was published on June 19, 2017. It is possible that in the meantime other information became available. For the latest information, including the official SmPC's, please refer to website of the MEB [www.cbq-meb.nl](http://www.cbq-meb.nl)*