

IMPORTANT MEDICINE SAFETY INFORMATION

TOPICAL STEROID - RISK OF WITHDRAWAL REACTIONS

13 July 2022

Dear Healthcare Professional,

The following holders of certificates of registration (HCRs), Aspen Pharmacare, GlaxoSmithKline (Pty) Ltd and Glenmark Pharmaceuticals South Africa (Pty) Ltd, in collaboration with the South African Health Products Regulatory Authority (SAHPRA), wish to draw your attention to the following important safety information associated with topical corticosteroid containing medicines registered in South Africa. This safety issue was based on a review of the available evidence conducted by the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).

Summary

- Rare and severe adverse effects can occur on stopping treatment with topical corticosteroids, particularly after long-term continuous or inappropriate use of moderate-to-high potency products.
- There are two distinct clinical presentations of topical corticosteroid withdrawal: red burning skin or papulopustular rashes (the latter include steroid rosacea and perioral/periorificial dermatitis).

Advice to healthcare professionals

- Long-term continuous or inappropriate use of topical corticosteroids, particularly those of moderate to high potency, can result in the development of rebound flares after stopping treatment. There are reports of flares manifesting as dermatitis with intense redness, stinging, and burning that can spread beyond the initial treatment area.
- When prescribing a topical corticosteroid, consider the lowest potency needed and restrict use to the shortest duration that is effective.
- Advise patients on the amount of product to be applied, as underuse can prolong treatment duration.
- Inform patients how long they should use a topical corticosteroid, especially on sensitive areas such as the face and genitals.
- Inform patients to return for medical advice if their skin condition worsens while using topical corticosteroids.
- Advise patients as to when it would be appropriate to re-treat without a consultation, and when to seek medical advice.
- For patients currently on long-term topical corticosteroid treatment, consider reducing potency or frequency of application (or both).

Advice for patients, parents and carers:

- Topical corticosteroids are used on the skin to reduce inflammation.
- When used correctly, they are safe and effective treatments for a variety of skin disorders.
- Always apply topical corticosteroids as instructed and consult the Patient Information Leaflet provided with your medicine.
- Seek medical advice before using a topical corticosteroid on a new body area as some areas of the body are more prone to side effects.
- Very infrequent cases of severe skin reactions have been reported in long-term users of topical corticosteroids after they stop using them.
- If your skin worsens within 2 weeks of stopping a topical corticosteroid, do not start treatment again without consulting your doctor, unless previously advised to do so.

- As well as the known side effects associated with using too much of a topical corticosteroid or with using it for too long, remember that using too little can prolong treatment time and increase the risk of side effects.
- Ask your prescriber or pharmacist if you have any questions about your medicines or are concerned about side effects.

The Professional Information (PI) and Patient Information Leaflet (PIL) will be updated accordingly

Healthcare professionals are urged to report any adverse drug reactions (ADRs) or product quality issues to SAHPRA via the e-Reporting link available on the SAHPRA website (www.sahpra.org.za). Alternatively, please complete the ADR reporting form accessible via the SAHPRA website and email it to adr@sahpra.org.za. Additionally, reporting can be done via Med Safety App. The App can be downloaded into a smart mobile phone through google Play or App store. For more information on Med Safety App, please visit SAHPRA website. For more information on ADR reporting of products listed below, please contact the SAHPRA vigilance unit at pvqueries@sahpra.org.za or alternatively use the contact details indicated below:



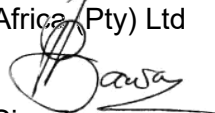
Table 1: Company Products

Company	Product name	Active ingredient	Registration Number	Contact details
Aspen Pharmacare	Aspen Mometasone Cream	Mometasone furoate	A38/13.4.1/0668	Tel: +27 800 118 088 Fax: +27 11 239 6303 drugsafety@aspenpharma.com
	Cortoderm Cream	Fluocinolone acetonide	L/13.4.1/42	
	Cortoderm Ointment	Fluocinolone acetonide	L/13.4.1/29	
	Dilucort Cream	Hydrocortisone acetate	R/13.4.1/21	
	Dilucort Ointment	Hydrocortisone acetate	R/13.4.1/20	
	Dovate Cream	Clobetasol propionate	27/13.4.1/0316	
	Dovate Ointment	Clobetasol propionate	27/13.4.1/0122	
	Lenovate Cream	Betamethasone valerate equivalent to Betamethasone	27/13.4.1/0493	
	Lenovate Ointment	Betamethasone valerate equivalent to Betamethasone	27/13.4.1/0308	
	Mylocort Cream	Hydrocortisone acetate	P/13.4.1/93	
	Mylocort Ointment	Hydrocortisone acetate	P/13.4.1/112	
	Persivate Cream	Betamethasone valerate equivalent to Betamethasone	L/13.4.1/382	
	Persivate Ointment	Betamethasone valerate equivalent to Betamethasone	L/13.4.1/395	
GlaxoSmith Kline (Pty) Ltd	Cutivate Cream	Fluticasone propionate	27/13.4.1/0441	Tel: +27 10 300 1000 aereporting.za@gsk.com
Glenmark Pharmaceuticals South Africa (Pty) Ltd	Synalar Gel	Fluocinolone acetonide	B/13.4.1/133	Tel: +27 11 564 3900 pv@glenmarkpharma.co.za
	Synalar Cream	Fluocinolone acetonide	G1396 (Act 101/1965)	
	Synalar Ointment	Fluocinolone acetonide	G1397 (Act 101/1965)	
	Synalar-N Cream	Fluocinolone acetonide/ Neomycin sulphate	G1400 (Act 101/1965)	
	Synalar-N Ointment	Fluocinolone acetonide/ Neomycin sulphate	G1401 (Act 101/1965)	
	Synalar-C Cream	Fluocinolone acetonide/ Clioquinol	G1398 (Act 101/1965)	
Synalar-C Ointment	Fluocinolone acetonide/ Clioquinol	G1399 (Act 101/1965)		

References

1. Medicines and Healthcare products Regulatory Agency (MHRA); Drug Safety Update; Volume 15, Issue 2: September 2021: 1.

Yours faithfully,

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