

IMPORTANT MEDICINES SAFETY INFORMATION

TOPICAL STEROID - RISK OF WITHDRAWAL REACTIONS

24 October 2022

Dear Healthcare Professional,

Adcock Ingram Ltd as directed by the South African Health Products Regulatory Authority (SAHPRA) wish to inform you about the risk of withdrawal reactions associated with the use of topical steroid containing medicines. 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).

Background on the safety concern

- 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).

The Professional Information (PI) and Patient Information Leaflets (PILs) of topical steroid containing medicines will be updated to appropriately reflect the below safety information.

Advice for 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 such flares taking the form of a 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.
- Advise patients on the amount of product to be applied, 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 corticosteroid, and advise them when it would be appropriate to re-treat without a consultation.
- For patients currently on long-term topical corticosteroid treatment, consider reducing potency or frequency of application (or both).

Advice for healthcare professionals to provide to parents and carers:

- Topical corticosteroids are used on the skin to reduce inflammation.
- When used correctly, they are safe and effective treatments for 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 shortly after stopping a topical corticosteroid, do not start treatment again without consulting your doctor, unless they have previously advised you should 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 certain adverse effects.
- Ask your prescriber or pharmacist if you have any questions about your medicines or are concerned about side effects.

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: Topical steroid containing medicines

Company	Product	API	Registration number	Schedule	Contact details
Adcock Ingram Limited	Advantan cream	Methylprednisolone Aceponate	X/13.4.1/384	4	Tel: 011 635 0134 Fax: 086 553 0128 Email: Adcock.Aereports@adcock.com
	Advantan ointment	Methylprednisolone Aceponate	X/13.4.1/385	4	
	Advantan milk	Methylprednisolone Aceponate	32/13.4.1/0362	4	
	Advantan fatty ointment	Methylprednisolone Aceponate	X/13.4.1/38	4	
	Advantan scalp solution	Methylprednisolone Aceponate	32/13.4.1/0361	4	
	Fucibet cream	Betamethasone valerate and Fusidic acid anhydrous	45/13.4. 1/0678	4	
	Fucidin H	Fucidic acid and hydrocortisone acetate	45/13.4.1/0568	4	
	Travocort	Difluocortolone Valerate and Isoconazole Nitrate	N/13.4.1/ 171	4	
	Pevisone cream	Econazole nitrate + Triamcinolone acetonide	Q13.4.1/0220	4	
	Locoid Lotion	Hydrocortisone Butyrate	B/13.4.1/108	4	
	Locoid Crelo	Hydrocortisone Butyrate	34/13.4.1/0221	4	
	Locoid Ointment	Hydrocortisone Butyrate	H/13.4.1/109	4	
	Locoid Cream	Hydrocortisone Butyrate	11/13.4.1/107	4	
	Locoid Lipocream	Hydrocortisone Butyrate	W/13.4.1/355	4	
Stopitch cream	Hydrocortisone	G2212	2		

Yours faithfully

Tammy Chetty
Responsible Pharmacist
Adcock Ingram Limited

References:

1. South African Health Products Regulatory Authority (SAHPRA) letter dated 21 February 2022. Re: topical steroid - risk of withdrawal reactions. Reference: Topical corticosteroids – PVC115_02Feb22
2. South African Health Products Regulatory Authority (SAHPRA) letter dated 27 June 2022 Topical corticosteroids Risk of withdrawal reactions - PVC 117 01June2022
3. Medicines and Healthcare products Regulatory Agency (MHRA) Research and analysis - Topical steroid withdrawal reactions: a review of the evidence. Published 15 September 2021. Available at <https://www.gov.uk/government/publications/topical-steroid-withdrawal-reactions-a-review-of-the-evidence/topical-steroid-withdrawal-reactions-a-review-of-the-evidence>
4. Medicines and Healthcare products Regulatory Agency (MHRA) monthly newsletter. Volume 15 Issue 2 September 2021. Topical corticosteroids: Information on the Risk of Topical Steroid Withdrawal Reactions