Organon South Africa (Pty) Ltd
(Reg. No. 2020 / 543929 / 07)
Spaces, 1st Floor
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IMPORTANT MEDICINE SAFETY INFORMATION

Initial Date: 12 December 2022

Final Approval Date: 24 April 2025

Dear Healthcare Professional

RE: TOPICAL CORTICOSTEROIDS – RISK OF WITHDRAWAL REACTIONS

Organon South Africa (Pty) Ltd as directed by the South African Health Products Regulatory Authority (SAHPRA), would like to inform you of the risk of withdrawal reactions associated with inappropriate and long-term use of topical corticosteroids.

The Professional Information (PI) and Patient Information Leaflet (PIL) of topical corticosteroid containing medicines will be amended to reflect the above safety information.

Background on Safety Concern

The safety issue was based on the available data from the Medicines & Healthcare products Regulatory Agency (MHRA). The data indicated that rare and severe adverse effects can occur on stopping treatment with topical corticosteroids, often after long-term continuous or inappropriate use of moderate to high potency products.

There are two distinct clinical presentations of topical steroid withdrawal:

- Red burning skin.
- Papulopustular rashes – these 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 (Topical Steroid Withdrawal Syndrome) – 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.
- It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment, a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.
- 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.

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- 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 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 to Healthcare Professionals to provide to Patients and Carers

- Topical corticosteroids are used on the skin to reduce inflammation and 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 eReporting 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@sahpa.org. Additionally, reporting can be done via the 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:

Company	Active Ingredient (s)	Product Name	Registration number	Contact details
Organon South Africa (Pty) Ltd	Mometasone furoate	Elocon Cream	V/13.4.1/272	Tel: 087 106 9655 Email: dpoc.zaf@organon.com
	Mometasone furoate	Elocon Lotion	X/13.4.1/266	
	Mometasone furoate	Elocon Ointment	V/13.4.1/273	
	Mometasone furoate	Elica Cream	31/13.4.1/0544	
	Mometasone furoate	Elica Lotion	31/13.4.1/0590	

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	Mometasone furoate	Elica Ointment	31/13.4.1/0545	
	Mometasone furoate	Elomet Cream	31/13.4.1/0546	
	Mometasone furoate	Elomet Lotion	31/13.4.1/0591	
	Mometasone furoate	Elomet Ointment	31/13.4.1/0547	
	Betamethasone dipropionate	Diprosone Cream	F/13.4.1/17	
	Betamethasone dipropionate	Diprosone Ointment	F/13.4.1/18	
	Betamethasone dipropionate + salicylic acid	Diprosalic Lotion	L/13.4.1/66	
	Betamethasone dipropionate + salicylic acid	Diprosalic Ointment	H/13.4.1/32	
	Betamethasone Dipropionate + gentamicin sulphate	Diprogenta Cream	F/13.4.1/223	
	Betamethasone dipropionate + gentamicin sulphate	Diprogenta Ointment	F/13.4.1/224	
	Clotrimazole + betamethasone dipropionate	Lotriderm Cream	R/13.4.1/38	

Yours faithfully

Nonhlanhla Sibiya

Electronically signed by: Nonhlanhla Sibiya
Reason: Quality Approver
Date: Apr 24, 2025 12:15 GMT+2

Nonhlanhla Sibiya
Responsible Pharmacist and Quality Lead

NDTshambuluka

Electronically signed by: NDTshambuluka
Reason: Approved
Date: Apr 24, 2025 13:25 GMT+2

Doris Tshambuluka
Organon PV Responsible