

August 7, 2024

Audience

Healthcare professionals including family physicians, general practitioners, and pharmacists.

Key messages

Teva Canada Ltd. is implementing a Type I recall to Consumer level for the following ratio-ECTOSONE (TEVA-ECTOSONE) lots:

Product: ratio-ECTOSONE (TEVA-ECTOSONE)			
0.1% regular lotion, 60 mL; DIN00750050			
Lot	Expiry	Lot	Expiry
686589	8/31/2024	688546	9/30/2025
686592	8/31/2024	688547	9/30/2025
686652	9/30/2024	688825	12/31/2025
686653	9/30/2024	688826	12/31/2025
687324	1/31/2025	690415	12/31/2026
687325	1/31/2025	690416	1/31/2027
687517	2/28/2025	690417	1/31/2027
687518	2/28/2025	690418	1/31/2027
0.05% mild lotion, 60 mL; DIN 00653209			
Lot	Expiry		
690516	1/31/2026		



Please return ratio-ECTOSONE (TEVA-ECTOSONE) lotion product to point of purchase as it is not proper for use.

Risk of exposure to a degradation product of ratio-ECTOSONE (TEVA-ECTOSONE) lotion.



What is the issue?

1. An out of specification result for an individual unspecified degradant of ratio-ECTOSONE (TEVA-ECTOSONE) 0.05% mild lotion 60mL and ratio-ECTOSONE (TEVA-ECTOSONE)0.1% Regular Lotion 60mL during stability testing.
2. Administrative name change and dosage application on ratio-ECTOSONE (TEVA-ECTOSONE) product label was not as per approved Health Canada database. Therefore, product on the market is labelled as ratio-ECTOSONE instead of TEVA-ECTOSONE.

Background information

ratio-ECTOSONE (TEVA-ECTOSONE) is for the topical management of allergic and inflammatory dermatoses responsive to corticosteroid therapy. These disorders include: psoriasis, atopic eczema, infantile eczema, nummular eczema, pruritus ani and vulvae, neurodermatitis (lichen simplex chronicus), intertrigo, contact dermatitis, seborrheic dermatitis, exfoliative dermatitis, solar dermatitis, stasis dermatitis and dyshidrosis. Refractory psoriasis may be treated with Ectosone regular especially in conjunction with the hydration technique of occlusive dressings. Ectosone mild contains a lower concentration (half strength) of betamethasone and is indicated for maintenance therapy after the acute phase has been brought under control, for less severe conditions and for extensive lesions involving large areas of the body surface.

Considering that the out of specification impurity results exceed the toxicological report's proposed limit, the effect in patients cannot be fully assessed. Consequentially, the probability of experiencing adverse events following exposure to the affected product cannot be ruled out. Moreover, the severity or likelihood of occurrence of these adverse events cannot be determined.

Additional Information

Consumers should return to point of purchase any ratio-ECTOSONE (TEVA-ECTOSONE) Lotion they have in their possession. Consumers should contact their health care professional for more information.

Health Care Practitioners should ensure all listed Lot# of ratio-ECTOSONE (TEVA-ECTOSONE) be discarded.

Any case of side effect or other serious or unexpected side effects in patients receiving ratio-ECTOSONE (TEVA-ECTOSONE) should be reported to **Teva Canada Limited** at 1-800-268-4127 Ext 3.

Didier Reymond
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Original signed by
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References: Product Monograph Date of Revision: November 02, 2018