

The Medical Letter[®]

on Drugs and Therapeutics

Objective Drug Reviews Since 1959

Volume 57

April 27, 2015

ISSUE No.

1467

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IN BRIEF

Mechlorethamine Gel (*Valchlor*) for Cutaneous T-Cell Lymphoma

The FDA has approved a 0.016% gel formulation of the nitrogen mustard mechlorethamine (*Valchlor* – Actelion) for second-line topical treatment of patients with stage IA or IB mycosis fungoides, the most common type of cutaneous T-cell lymphoma. Topical nitrogen mustard has been used off-label for decades for this indication, usually as a pharmacy-compounded ointment, but no clinical trials evaluating its efficacy and safety have been done. Mechlorethamine is also available in an injectable formulation (*Mustargen* – Recordati) for the same and other indications.

FDA approval of *Valchlor* was based on a randomized, non-inferiority trial in 260 patients with stage IA, IB, or IIA mycosis fungoides comparing it to a 0.02% mechlorethamine compounded ointment, both applied once daily for up to 1 year. Response rates, based on a composite assessment of index lesion severity, were slightly higher with the gel (59% vs. 48%, which met prespecified criteria for noninferiority). Based on a Kaplan-Meier analysis, the estimated time to a 50% response rate was shorter with the gel than with the compounded ointment (26 weeks vs. 42 weeks). It was also estimated that at least 90% of the responses in

both treatment arms would be maintained for ≥ 10 months, the maximum follow-up period in the trial.

No serious drug-related adverse effects were observed, and no systemic absorption of the drug was detected. About 20% of patients treated with the gel and about 17% of those treated with the ointment withdrew from the study because of skin irritation, which has always been the most troublesome side effect of topical mechlorethamine.¹

A thin layer of mechlorethamine gel should be applied to each affected area of the skin once daily. The drug should be stopped if skin ulceration, blistering, or moderately severe or severe dermatitis occurs. Treatment can be restarted at a frequency of once every 3 days for 1 week and, if tolerated, can be increased to every other day for another week, and then to once daily. The gel should be stored in the refrigerator and applied within 30 minutes of removing it from the refrigerator. The cost of a 60-g tube is \$2900.² ■

1. SR Lessin et al. Topical chemotherapy in cutaneous T-cell lymphoma: positive results of a randomized, controlled, multicenter trial testing the efficacy and safety of a novel mechlorethamine, 0.02%, gel in mycosis fungoides. *JAMA Dermatol* 2013; 149:25.
2. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. April 5, 2015. Reprinted with permission by First Databank, Inc. All rights reserved. ©2015. www.fdbhealth.com/policies/drug-pricing-policy.

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