

## STEPS

### New Drug Reviews

### Dapsone (Aczone) 5% Gel for the Treatment of Acne

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Dapsone is an antibiotic that has been used since the 1940s for the treatment of leprosy and skin disorders such as dermatitis herpetiformis and nodulocystic acne. Dapsone (Aczone) 5% gel is approved by the U.S. Food and Drug Administration (FDA) for the treatment of acne vulgaris in adults and children older than 12 years. Although dapsone has antibacterial and anti-inflammatory activity, the mechanism of action in the treatment of acne is unknown.

Drug	Dosage	Dose form	Cost*
Dapsone (Aczone) 5% gel	Apply twice daily	30-g tube	\$146

\*—Estimated retail price (rounded to the nearest dollar) of one month's treatment based on information obtained at <http://www.drugstore.com> (accessed January 14, 2010).

#### SAFETY

Orally administered dapsone is known to cause hematologic reactions, including met-hemoglobinemia; hemolysis, especially in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency; and agranulocytosis. These reactions are less likely with topical treatment. Hemolytic anemia has been shown not to occur in patients with G6PD deficiency with acne who were treated with topical therapy.<sup>1,2</sup> However, the manufacturer warns of an increased risk of hemolysis in patients who use a combination of topical dapsone and oral trimethoprim/sulfamethoxazole (Bactrim, Septra).<sup>3</sup> Dapsone gel should not be used in patients who are taking oral dapsone or antimalarial medications because of the potential for hemolytic reactions. Dapsone gel is FDA pregnancy category C; safety has not been established in breastfeeding mothers.<sup>3</sup>

#### TOLERABILITY

Adverse effects of dapsone gel therapy occur mainly at the site of application. The most common are dryness (16 percent), erythema (13 percent), and oiliness/peeling (13 percent).<sup>3</sup> These reactions are most likely caused by the gel vehicle. Application of dapsone gel followed by benzoyl peroxide causes a temporary local yellow or orange discoloration of the skin and facial hair; this reaction typically resolves in one to eight weeks.<sup>3</sup>

#### EFFECTIVENESS

Studies show that dapsone gel has modest effectiveness in the treatment of moderately severe inflammatory and noninflammatory acne. Two studies show a clinical success rate of 40.5 versus 32.8 percent with placebo over a 12-week period (number needed to treat = 13), as defined by global assessment and a statistically significant reduction in the percentage of lesions.<sup>4,5</sup> Dapsone gel is more effective in reducing inflammatory lesions (i.e., papules, pustules, and nodules) than noninflammatory lesions (i.e., open and closed comedones), with up to 50 percent reduction by 12 weeks of use, compared with a 42 percent response with placebo.<sup>4</sup> For comparison, large studies of patients with moderately severe acne show up to 90 percent clearing of lesions after six to eight weeks of retinoid plus benzoyl peroxide therapy.<sup>6</sup> Although there may be a response to initial treatment with dapsone gel within one to two weeks, this rate is not faster than the response to a combination of a retinoid and benzoyl peroxide.

Dapsone gel has not been directly compared with more established therapies (e.g., topical retinoid monotherapy) or combination topical therapies (e.g., benzoyl peroxide plus either a topical antibiotic or a retinoid).

#### PRICE

A 30-g tube of dapsone 5% gel costs approximately \$146. This is higher than the cost of a 20-g tube of tretinoin (Retin-A) 0.025% gel (\$40 [brand: \$81]) or a 30-g tube of clindamycin (Cleocin) 1% gel (\$18 [brand: \$63]).

#### SIMPLICITY

A pea-sized amount of dapsone gel should be applied in a thin layer to the acne-affected areas twice daily and rubbed in gently and completely.<sup>3</sup> Although erythema and dryness are common adverse effects, they are generally mild and rarely require discontinuation of treatment. For more severe reactions, dapsone gel therapy should be discontinued and alternate topical medications substituted.

### Bottom Line

Topical dapsone gel will decrease the percentage of lesions in patients with mild to moderate acne, especially inflammatory lesions. Although not directly compared, dapsone gel has lower response rates than currently available topical treatments that are less expensive. It may have a role in those few patients who are allergic to or cannot tolerate other treatments, but should not be used as first-line therapy.

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Author disclosure: Nothing to disclose.

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