

VEHICLES MATTER: DESIGNED FOR PURPOSE



Leon Kircik MD

Janus kinase (JAK) inhibitors, which have been used in a range of disease states from rheumatology to gastroenterology, have been finally adopted into dermatology. These agents are rapidly changing the ways that dermatologists treat a range of inflammatory skin diseases, particularly atopic dermatitis (AD).¹

There are several oral JAK formulations available in the United States market. The first topical cream formulation of a JAK inhibitor is ruxolitinib cream 1.5%, which is approved for the management of nonsegmental vitiligo and short-term non-continuous use for mild to moderate atopic dermatitis in adults and children 12 or older. Current guidelines of care for the management of atopic dermatitis from the American Academy of Dermatology give a strong recommendation for ruxolitinib cream for adults with AD.²

The cream formulation contains several emollient and hydrating ingredients that leave no greasy residue after application. Both clinical trial data and real-world experience show that this unique topical JAK formulation offers versatility for prescribers and their patients with eczema as a safe and effective alternative to topical steroids.

As described in the pages ahead, the pivotal trials for ruxolitinib cream show that it provides notable and sustained skin clearance in individuals as young as age 12. In the randomized, double-blind, vehicle-controlled, 8-week phase 3 clinical trials (TRuE-AD1/2), 53.8% and 51.3% (TRuE-AD1 and TRuE-AD2, respectively) of subjects treated with ruxolitinib cream 1.5% achieved IGA success vs 15.1% and 7.6% in the vehicle arms, respectively, at week 8. Greater percentages of ruxolitinib-treated subjects achieved EASI-75 compared to vehicle (62.1% and 61.8% vs 24.6% and 14.4%, respectively).³ Given the incidence and impact of eczema on pediatric patients, it is worth noting that a pooled analysis of data from the two phase 3 trials found that 8-week treatment success (IGA) and EASI-75 rates for subjects aged 12 to 17 were comparable to the rates for those aged 18 and older.⁴

There is also favorable data to support the use of ruxolitinib cream on various anatomic areas. For example, when it was assessed for the treatment of AD in the head and neck region, nearly two-thirds of patients were clear or almost clear at the first follow up.⁵ As noted in the pages ahead, other topical treatments indicated for AD may be associated with increased irritation and burning when applied to the head and neck area.² For the management of chronic hand eczema, ruxolitinib is associated with significant rates of skin clearance at week 4, even among patients who had failed other topical and oral therapies.^{6,8}

What may be most striking in the clinical trial data and real-world experience with ruxolitinib cream 1.5% is the rapid reduction of itch. Among multiple data analyses demonstrating substantial and rapid reduction of itch, a pooled analysis of the phase 3 trials found ruxolitinib cream to improve itch as early as 12 hours following the first application.⁷ Considering that eczema is often called “the itch that rashes,” the rapid and substantial improvement in pruritus associated with ruxolitinib cream use may be an important asset in patient care. Despite these impactful findings, there remains hesitation to steer away from topical steroids in daily practice. One possible reason for this is the perception of the safety profile of JAK inhibitors.

While the label for ruxolitinib cream 1.5% has a boxed warning consistent with other JAK inhibitors, oral ruxolitinib, which was approved for intermediate or high-risk myelofibrosis and polycythemia vera in 2011, has no boxed warning! This is certainly perplexing and challenging to explain, especially since the data for the cream overall show low rates of significant adverse events.²

The topical cream formulation of ruxolitinib cream 1.5% has emerged as an effective and safe non-steroidal treatment option for a chronic disease where long-term topical steroid use is not recommended. Additionally, this cream's moisturizing, non-greasy formulation makes it a very user friendly and favorable option for our patients.

As always, "VEHICLES MATTER"

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DISCLOSURE

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