

Altreno[™] (tretinoin) – New drug approval

- On August 23, 2018, the FDA approved [Ortho Dermatologics Altreno \(tretinoin\) 0.05% lotion](#) for the topical treatment of acne vulgaris in patients 9 years of age and older.
 - Altreno is the first lotion formulation of tretinoin.
- [Acne](#) is a skin condition that occurs when hair follicles become plugged with oil and skin cells. This often causes whiteheads, blackheads or pimples and appearing on the face, forehead, chest, upper back and shoulders. Acne is most common among people ages 12 to 24, though it can affect people of all ages. Depending on its severity, acne can cause emotional distress and scar the skin.
- [The American Academy of Dermatology](#) states that acne is the most common skin problem in the United States affecting up to 50 million Americans. Acne can occur at any stage of life and may continue into one's 30s and 40s. Acne occurring in adults is increasing, affecting up to 15% of women.
- Tretinoin is a metabolite of vitamin A that binds with high affinity to specific retinoic acid receptors located in both the cytosol and nucleus. Tretinoin activates three members of the retinoic acid nuclear receptors which act to modify gene expression, subsequent protein synthesis, and epithelial cell growth and differentiation.
- The safety and efficacy of Altreno was evaluated in two vehicle controlled phase 3 studies enrolling 1,640 patients.
 - At week 12, 16.5% and 19.8% of patients in trials 1 and 2, respectively, achieved improvements in acne symptoms with tretinoin 0.05% lotion, compared to only 6.9% and 12.5% with vehicle.
 - Patients treated with Altreno saw a mean absolute reduction of 17.8 and 21.9 in non-inflammatory lesions in trials 1 and 2, compared to 10.6 and 13.9 in patients treated with vehicle.
 - Patients treated with Altreno saw a mean absolute reduction of 13.1 and 13.9 in inflammatory lesions in trials 1 and 2, compared to 10.6 and 10.7 in patients treated with vehicle.
- Warnings and precautions of Altreno include skin irritation, fish allergies, ultraviolet light and environmental exposure.
- The most common adverse reactions ($\geq 1\%$ and greater than vehicle) with Altreno use were dryness, pain, erythema, irritation and exfoliation (all at the application site).
- The recommended dose of Altreno is to apply a thin layer to affected areas once daily. Avoid eyes, mouth, paranasal creases, and mucous membranes.
- Valeant Pharmaceuticals plans to launch Altreno by the 4th quarter of 2018. Altreno will be available as a tretinoin 0.05% lotion.