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There Are 'Clear' Benefits to Staying on Treatment, so What's Stopping Rosacea Patients?



Prescribing Info



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There Are ‘Clear’ Benefits to Staying on Treatment, so What’s Stopping Rosacea Patients?

April is Rosacea Awareness Month, a month designated to recognizing the impact of the chronic skin condition which affects 16 million people in the US alone.^{1,2} Rosacea is a life-long disease that *can* be managed quite effectively, so let’s discuss some reasons why that isn’t always the case.

Many barriers exist which prevent rosacea sufferers from achieving clearer skin—from ineffective treatments leading to a lack of adherence, through to low commitment to their ongoing therapy.³ These barriers are common in chronic conditions; but addressing both treatment choice and patient commitment can make a real difference for outcomes in your rosacea patients.³

Why prescribe your patient a high-dose antibiotic when bacteria isn’t the cause of their rosacea?

Rosacea is an inflammatory skin condition which is not caused by bacteria, therefore the appropriate treatment for papulopustular rosacea is not a high-dose antibiotic.⁴ However, high-dose tetracyclines, such as doxycycline 100 mg, tend to be the main rosacea prescription by dermatologists.⁵ High-dose antibiotics can increase the risk of antibiotic resistance and are coupled with unwanted side effects,⁶ which are a key driver of poor patient adherence.

Due to this, Galderma has developed a unique non-antibiotic dose doxycycline formulation in a capsule, powerful enough to reduce the inflammatory lesions of rosacea, minus the risk of antibacterial effects.^{7,8}

ORACEA (doxycycline, USP) 40 mg* Capsules are the only FDA-approved oral therapy for the treatment of papulopustular rosacea, and they have been specifically designed to put your patients’ needs at the forefront.⁹

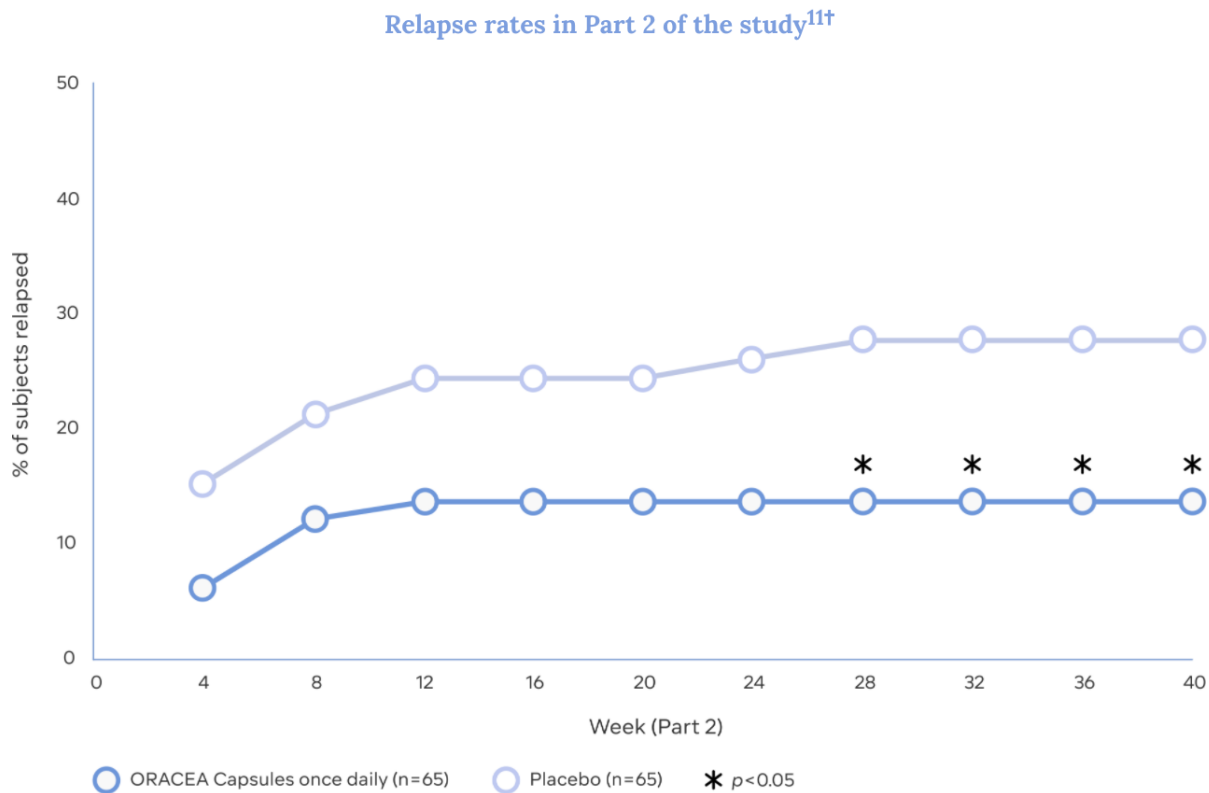
The safety and efficacy of ORACEA Capsules in the treatment of inflammatory lesions of rosacea has been evaluated in two randomized, placebo-controlled, multicenter, double-blind, 16-week Phase 3 trials.⁷ Across both studies, 537 subjects were involved, of which 269 with rosacea were taking ORACEA Capsules (10 to 40 papules and pustules and two fewer nodules). The mean change in lesion

count for ORACEA Capsules vs placebo for study 1 was **-11.8** vs -5.9, and for study 2, was **-9.5** vs -4.3. The most common adverse events (>2%) were nasopharyngitis, sinusitis, diarrhea, hypertension and aspartate aminotransferase (AST) increase.⁷

Choose a treatment that patients will stay on and provides long-term benefits

Rosacea can have a huge burden on patients, which can be damaging to their quality of life.¹⁰ Your patients will be looking to you for treatment options which target their visible inflammation and improve signs and symptoms of papulopustular rosacea, while reducing relapses.

Maximizing the duration of remission is important. In a recent study, ORACEA Capsules have shown that their continued use as a monotherapy significantly reduces relapse rates, with 86% of the patients treated with ORACEA Capsules maintaining treatment success or as long as 10 months (p<0.005)¹¹



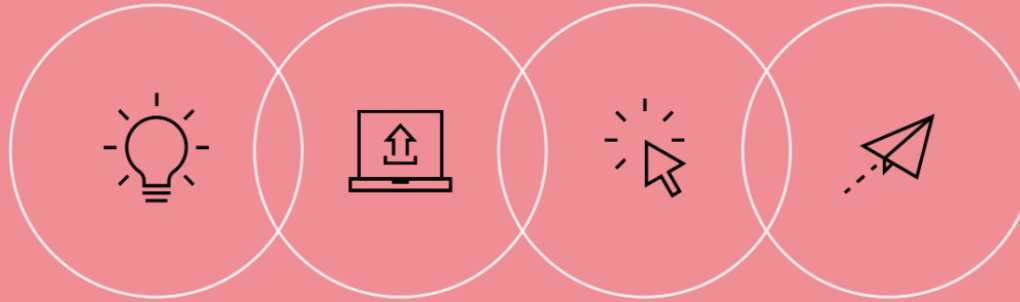
†A two-part study assessing relapse, efficacy, and safety of ORACEA Capsules in patients with moderate or severe rosacea over 52 weeks (n=235). Part 1 was a 12-week multicenter, open-label study in which patients were treated with ORACEA Capsules and metronidazole gel, 1% once daily. Part 2 was a 40-week multicenter, randomized, double-blind, placebo-controlled study in which patients who achieved treatment success in Part I were eligible to be randomized to receive either ORACEA Capsules or placebo once daily for up to an additional 40 weeks. Subjects who relapsed during Part 2 were discontinued. The data points in the graph for Part 1 were calculated retrospectively after the patients who moved to Part 2 were randomized. Relapse was defined as a return to baseline Investigator Global Assessment (IGA) or lesion count, or any other necessary change in treatment. Both treatments were safe and well tolerated in this study. Adverse events (AEs) were generally mild or moderate in severity during both parts of the study. A similar number of AEs were reported in both the ORACEA Capsules and placebo groups (12 subjects in each group), and no serious or gastrointestinal AEs were considered to be treatment related.¹¹ Most common treatment related adverse events $\geq 2\%$ included: Part 1: Nasopharyngitis Part 2: Nausea

Your patients are more likely to stick with a treatment which may keep their skin 'clear' for longer. Choosing a treatment that helps improve overall adherence may get more patients to 'clear'.

Tackling rosacea requires both treatment and support

ORACEA Capsules are key to helping combat the physical symptoms rosacea sufferers face, however your patients also need support once they have left the clinic. That's why, for Rosacea Awareness Month, Galderma is launching a platform called **Rosacea Space**, designed to allow patients to connect with and inspire other rosacea sufferers, through an array of creative submissions.

Create – Upload – Explore – Share



By encouraging your patients to connect with the wider rosacea community on **Rosacea Space**, they can become a better advocate for their own health, be supported by a community which face similar daily experiences, be inspired to adhere to their treatment, and ultimately work towards achieving 'clearer' skin.

Click oracea.com/hcp to learn more about ORACEA Capsules

Click [here](#) to direct your patients to Rosacea Space

Important Safety Information

Indication: ORACEA[®] (doxycycline, USP) 40 mg* Capsules are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. ORACEA Capsules do not lessen the facial redness caused by rosacea. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (>2%) in patients treated with ORACEA Capsules were nasopharyngitis, sinusitis, diarrhea, hypertension and aspartate aminotransferase increase.

Warnings/Precautions: ORACEA Capsules should not be used to treat or prevent infections. ORACEA Capsules should not be taken by patients who have a known hypersensitivity to doxycycline or other tetracyclines. ORACEA Capsules should not be taken during pregnancy, by nursing mothers, or during tooth development (up to the age of 8 years). Although photosensitivity was not observed in clinical trials, ORACEA Capsules patients should minimize or avoid exposure to natural or artificial sunlight. The efficacy of ORACEA Capsules treatment beyond 16 weeks and safety beyond 9 months have not been established.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/safety/medwatch/ or call 1-800-FDA-1088.

View full [Prescribing Information](#) here

*30 mg immediate release and 10 mg delayed release beads

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