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Industry News

Patients with acne report positive experience with minocycline gel. June 26, 2017. Healio Dermatology News.

<https://www.healio.com/dermatology/acne/news/online/%7Bf796861b-b8ef-469a-be98-12528991b47e%7D/patients-with-acne-report-positive-experience-with-minocycline-gel>

BioPharmX Corp. recently presented results of its phase 2b study of BPX-01 for treating moderate-to-severe acne vulgaris showing that patients reported a positive experience with the topical minocycline gel at the Alabama Dermatology Society's Summer Symposium in Sandestin, Florida. The study findings were discussed at a presentation by James Q. Del Rosso, DO, founder of JDR Dermatology Research, Las Vegas, and a poster presentation at the meeting, according to a news release from BioPharmX. New research findings regarding BPX-01, a topical hydrophilic gel formulation of minocycline, included 79% of surveyed patients at week 12 reporting that the 2% formulation of BPX-01 was easy to use and apply, and 86% reporting they would use the product again, according to the release. "Efficacy and safety are crucial to dermatologists and their acne patients, but just as important is patient compliance," said G. Scott Herron, MD, PhD, BioPharmX medical director, and board-certified dermatologist, stated in the release. "Phase 2b subjects told us BPX-01 is easy to use and they expressed a willingness to use it again. We believe this gives BPX-01 a significant advantage over topical therapies that have irritating side effects like rashes, dryness or itching, or oral therapies that are associated with headaches, dizziness or diarrhea." Previously presented phase 2b data showed that patients treated with the 2% formulation BPX-01 had a 59% reduction in acne lesions, compared with 44% for vehicle. There was at least a two-grade reduction in investigator global assessment and clear to almost clear for 25% of patients, according to the release. There were no serious drug-related adverse events reported. BioPharmX had previously reported the phase 2b data to investors, but this was the first presentation of the research at a medical conference. BPX-01 is the first topical gel formulation of minocycline that can penetrate the skin to deliver the antibiotic to the pilosebaceous unit, according to the release. BioPharmX reported it is conducting studies to confirm whether BPX-01 will effectively treat acne with lower dosages of the antibiotic with no or fewer adverse side effects.

BioPharmX reports Q1 results, acne treatment update. June 14, 2017. Healio Dermatology News.

<https://www.healio.com/dermatology/acne/news/online/%7B239bdc0c-2fe0-4ea5-99fe-9ae0710713f5%7D/biopharmx-reports-q1-results-acne-treatment-update>

BioPharmX Corporation reported financial results for the first quarter ending April 30, as well as an update on BPX-01, its investigational topical drug for acne. The specialty pharmaceutical company presented comprehensive phase 2b clinical data during a recent "State of Acne" symposium showing that BPX-01 2% achieved its primary endpoint, reducing the number of inflammatory lesions in acne patients by 59%, compared with 44% in vehicle. There were no serious drug-related adverse side effects experienced, and findings suggested it may also lessen the severity of lesions, according to a press release. A phase 3 program is expected to begin later this year, with BioPharmX reporting it is exploring a variety of funding alternatives, including both dilutive and non-dilutive financing options and strategic partnerships. "The enthusiasm investigators expressed about our phase 2b trial results confirms our excitement about BPX-01 as we finalize plans for phase 3 research," Anja Krammer, BioPharmX president, stated in the release. Total operating expenses for the first quarter were \$5 million, compared with \$4.5 million in the prior fiscal year's first quarter. The increase resulted primarily from higher spending for the company's acne drug clinical trials, offset promotions related to the company's Violet product, according to the release. Net loss for the first

quarter of fiscal year 2018 was \$5.4 million, compared with a net loss of \$4.5 million during the same period a year earlier, BioPharmX reported. Reference: www.biopharmx.com

New Medical News

A New Perspective on Isotretinoin Treatment of Hidradenitis Suppurativa: A Retrospective Chart Review of Patient Outcomes. Huang CM, Kirchhof MG. *Dermatology*. 2017 Jun 23. doi: 10.1159/000477207. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28641306>

BACKGROUND: Hidradenitis suppurativa (HS) is a disease characterized by the development of painful, deep-seeded nodules and abscesses. Treatment guidelines include a combination of lifestyle, surgical, and medical interventions. Isotretinoin has not been included in the treatment guidelines due to the limited number of studies and conflicting reports of efficacy. **OBJECTIVES:** The purpose of this study is to evaluate the clinical response to isotretinoin in HS patients and to determine whether there is a particular patient population that may benefit more from this treatment. **METHODS:** A retrospective chart review was conducted on all HS patients treated with isotretinoin within the years of 2014-2016. Sex, age, weight, history of acne, Hurley stage, and treatment dose and duration were extracted from patient charts. **RESULTS:** Of the 25 patients included in the study, 32% (8/25) had no response, 32% (8/26) showed partial response, and 36% (9/25) demonstrated complete response to isotretinoin treatment. Complete response was seen only in Hurley stage I and II patients. Hurley III patients made up 50% of the non-responders. Those with any sort of treatment response were more likely to be female, younger, weigh less, and have a higher prevalence of acne compared to non-responders. **LIMITATIONS:** This is a retrospective chart review with a small sample size of 25 patients. **CONCLUSIONS:** Physicians should consider isotretinoin as a potential treatment for HS, as it may be beneficial in patients with mild and moderate disease and patients who are female, younger, weigh less, and have a personal history of acne.

Isotretinoin and lymecycline treatments modify the skin microbiota in acne. Kelh  la HL, Aho VTE, Fyhrquist N, et al. *Exp Dermatol*. 2017 Jun 21. doi: 10.1111/exd.13397. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28636791>

Oral retinoids and tetracyclines have a major role in acne treatment. Here, we report for the first time the effect of isotretinoin and lymecycline therapy on the skin microbiota in cheek, back and armpit swab samples of acne vulgaris patients using 16S ribosomal RNA (16S rRNA) gene amplicon sequencing. *Propionibacterium acnes* was the most common in sebaceous areas of healthy and untreated acne skin and more abundant in back than cheek samples. Five taxa, including a *Streptococcus* taxon, differed significantly between the cheek samples of healthy controls and acne patients, and acne severity was positively correlated with the abundance of *Propionibacterium*. Both treatments reduced clinical acne grades and the abundance of *Propionibacterium*, while the abundance of several other taxa was significantly higher in treated cheek samples compared with untreated ones. Less variation was observed in back samples and none in armpit samples. There were no differences in alpha diversity between control and acne patients in any of the sampled skin areas, but the diversity of the microbiota on the cheek and the back was significantly increased after acne treatments. This study provides insight into the skin microbiota in acne and how it is modulated by systemic acne treatment.

The pinhole method using an erbium: YAG laser for the treatment of papular acne scars. Lee SJ, Kim JM, Kim YK, et al. *Dermatol Ther.* 2017 Jun 16. doi: 10.1111/dth.12512. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28621453>

Papular acne scars are skin-colored or hypopigmented, soft and elevated lesions of the chin and trunk. Papular scars are one of the most difficult acne scars to treat. Herein, we reported two patients with papular acne scars on the chin that were successfully treated by the pinhole method using an Erbium (ER):YAG laser. Good cosmetic results were achieved in both patients. The side effects included mild, intra-, and post-procedural pain and erythema that resolved spontaneously within 2 weeks. The pinhole method with an Er:YAG laser could potentially be used as a safe and effective treatment for papular acne scars.

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A comparison of culture and PCR methods for identifying Propionibacterium acnes in lesions isolated from patients with acne. Naghdi N, Ghane M. *Turk J Med Sci.* 2017 Jun 12;47(3):967-972. doi: 10.3906/sag-1602-51. <https://www.ncbi.nlm.nih.gov/pubmed/28618752>

BACKGROUND/AIM: One of the factors that affect the occurrence of acne is the presence of Propionibacterium acnes. The present study was conducted to compare the culture and polymerase chain reaction (PCR) methods for identifying P. acnes in lesions isolated from patients with acne. MATERIALS AND METHODS: To examine the presence of P. acnes, 70 samples of acne lesions were collected. Microbial culture and the PCR molecular technique were used to identify P. acnes. RESULTS: Of the total of 70 samples, 14 cases (20%) were identified as P. acnes positive using microbial culture and 58 cases (82.85%) using PCR. The results obtained showed the lack of a relationship between the frequency of P. acnes and factors such as sex, family history of acne, and history of treatment with either of the techniques examined (i.e. the microbial culture and PCR). In contrast, a significant relationship was observed between the frequency of P. acnes and age with the culture method. CONCLUSION: Given the limitations in the identification of P. acnes using microbial culture, PCR is proposed as a better method with a higher efficiency.

Evaluation of a novel very high sun-protection-factor moisturizer in adults with rosacea-prone sensitive skin. Grivet-Seyve M, Santoro F, Lachmann N. *Clin Cosmet Investig Dermatol.* 2017 Jun 10;10:211-219. doi: 10.2147/CCID.S134857. eCollection 2017. <https://www.dovepress.com/evaluation-of-a-novel-very-high-sun-protection-factor-moisturizer-in-a-peer-reviewed-fulltext-article-CCID>

BACKGROUND/OBJECTIVE: Rosacea-prone sensitive skin requires high sun-protection factor (SPF) moisturizers. This study evaluated Daylong Extreme SPF 50+ lotion, a novel cream containing five ultraviolet filters, two emollients, and three skin conditioners. SUBJECTS AND METHODS: This was an open-label, single-center study. On day 1, before treatment, subjects answered a questionnaire on their skin conditions and sunscreen habits, and both subjects and dermatologist evaluated skin status. Subjects applied the product once daily in the morning to the face for 21 days, and after approximately 3-5 minutes they assessed tolerability and short-term cosmetic acceptability in a questionnaire and daily diary. On day 22, the dermatologist and subjects evaluated skin status for long-term tolerance and cosmetic acceptability. RESULTS: The study enrolled 44 individuals (mean age 58.8 years, 91% female). At baseline, most subjects (39 of 44) showed erythema, and ~30% showed dryness and scaling. Dermatologists noted four cases of pustules and one case of papules. After 21 days' treatment with the product, the dermatologist reported significantly less erythema, dryness and scaling, three cases of pustules and two cases of

papules. At baseline, ~75% of subjects noted a feeling of dryness, >50% reported tension, and nearly 25% reported tickling. After using the product for 21 days, subjects reported significantly less tension, dryness, and tickling. Some subjects noted itching and burning before and after using the product. One subject noted papules during treatment. Most subjects said that the product was pleasant, did not irritate the skin or cause stinging/burning, was easy to apply, quickly absorbed, and nongreasy, improved skin moisturization, helped prevent sun-provoked facial redness, did not worsen rosacea, and was easily incorporated into their skincare regimen. Half would switch to the product, and 80% of subjects would buy and recommend the product. CONCLUSION: The product was well tolerated in rosacea-prone subjects, producing objective and subjective improvements in skin status and symptoms.

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Differences in Dietary Glycemic Load and Hormones in New York City Adults with No and Moderate/Severe Acne. Burris J, Rietkerk W, Shikany JM, Woolf K. *J Acad Nutr Diet.* 2017 Jun 9. pii: S2212-2672(17)30334-9. doi: 10.1016/j.jand.2017.03.024. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28606553>

BACKGROUND: Glycemic index (GI) and glycemic load (GL) may be implicated in acne pathogenesis. **OBJECTIVE:** This cross-sectional study examined differences between GI/GL and biological factors associated with acne among adults with and without moderate/severe acne. Secondary objectives included examining differences between food-aggravated acne beliefs and acne-specific quality of life among adults with and without moderate/severe acne. **DESIGN:** As part of a cross-sectional study, participants completed a 5-day food record; blood draw to measure biological factors associated with acne (ie, glucose, insulin, insulin-like growth factor-1, insulin-like growth factor binding protein-3, and sex hormone-binding globulin concentrations); body composition assessment; and questionnaire to evaluate food-aggravated acne beliefs and acne-specific quality of life. Food records were analyzed using Nutrition Data Services for Research. **PARTICIPANTS:** Sixty-four participants (no acne, n=32; moderate/severe acne, n=32) from New York City, NY, were included in this study. **STATISTICAL ANALYSIS:** Independent sample t tests and Mann-Whitney tests examined differences in anthropometric measurements, dietary intakes, biological factors associated with acne, insulin resistance, and acne-specific quality of life between acne groups. A χ^2 test for independence assessed differences in food-aggravated acne beliefs between acne groups. **RESULTS:** Participants with moderate/severe acne consumed greater total carbohydrate (P=0.003), available carbohydrate (P<0.001), percent energy from carbohydrate (P<0.001), and GL (P<0.001) compared to participants without acne. Participants with moderate/severe acne had greater insulin (P=0.002) and insulin-like growth factor-1 (P=0.009) concentrations, greater insulin resistance (P=0.001), and lower sex hormone-binding globulin (P=0.015) concentrations compared to participants without acne. Although there were no differences between groups, 61% of participants reported food-influenced acne. Participants with moderate/severe acne reported a lower quality of life compared to participants without acne (P<0.001). **CONCLUSIONS:** The results from this cross-sectional study suggest a relationship between dietary carbohydrate, including GL, and acne. Future research is necessary to determine the effect of medical nutrition therapy on biological factors associated with acne and acne severity.

Clinical Reviews

Evidence-based recommendations for the management of acne fulminans and its variants. Greywal T, Zaenglein AL, Baldwin HE, et. Al. *J Am Acad Dermatol.* 2017 Jul;77(1):109-117. doi: 10.1016/j.jaad.2016.11.028. [http://www.jaad.org/article/S0190-9622\(16\)31116-1/fulltext](http://www.jaad.org/article/S0190-9622(16)31116-1/fulltext)

BACKGROUND: Acne fulminans (AF) is a severe variant of inflammatory acne. It typically manifests as an explosive worsening and ulceration of skin lesions, and can be associated with systemic symptoms. However, there is a paucity of evidence-based information and no clear guidelines concerning the classification and treatment of AF. **OBJECTIVE:** To better define the spectrum of AF and its variants, devise optimal therapeutic approaches, and identify areas of future research. **METHODS:** A panel of physicians with expertise in severe acne vulgaris was convened after a comprehensive literature review of severe acne variants. Priority topics were reviewed and presented by each panelist at a 5-hour conference. Following review of the audiotape and scribed notes from the conference, surveys were utilized to address points of controversy and to clarify consensus recommendations. **RESULTS:** Appropriate clinical case presentations and consensus survey questions were utilized to create final recommendations based on both the literature and the expert consensus. **LIMITATIONS:** Limited evidenced-based data and prospective studies in the literature concerning the treatment of AF is available. **CONCLUSION:** These guidelines better characterize AF and provide health care practitioners approaches to the classification, treatment, and prevention of AF and its variants.

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The Role of Polyphenols in Rosacea Treatment: A Systematic Review. Saric S, Clark AK, Sivamani RK, et al. *J Altern Complement Med.* 2017 Jun 26. doi: 10.1089/acm.2016.0398. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28626508>

OBJECTIVES: Various treatment options are available for the management of rosacea symptoms such as facial erythema, telangiectasia, papules and pustules, burning, stinging, and itching. Botanical therapies are commonly used to treat the symptoms. The objective of this review is to evaluate the use of polyphenols in rosacea treatment. **DESIGN:** PubMed, Embase, Biosis, Web of Knowledge, and Scopus databases were systematically searched for clinical studies evaluating polyphenols in the management of rosacea. **RESULTS:** Of 814 citations, 6 met the inclusion criteria. The studies evaluated licochalcone (n = 2), silymarin (n = 2), Crysanthellum indicum extract (n = 1), and quassia extract (n = 1). The studies only evaluated topical formations of stated polyphenols. Main results were summarized. **CONCLUSIONS:** There is evidence that polyphenols may be beneficial for the treatment of rosacea symptoms. Polyphenols appear to be most effective at reducing facial erythema and papule and pustule counts. However, studies included have significant methodological limitations and therefore large-scale, randomized, placebo-controlled trials are warranted to further assess the efficacy and safety of polyphenols in the treatment of rosacea.

Antibiotic Resistance in Acne Treatment. Adler BL, Kornmehl H, Armstrong AW. *JAMA Dermatol.* 2017 Jun 21. doi: 10.1001/jamadermatol.2017.1297. [Epub ahead of print] <http://jamanetwork.com/journals/jamadermatology/fullarticle/2631310>

Clinical Question: What is the evidence for antibiotic resistance in acne, and how does resistance affect treatment? Bottom Line: Use of topical and systemic antibiotics for acne is associated with formation of resistance in *Propionibacterium acnes* and other bacteria, with clinical consequences. Guidelines recommend resistance reduction strategies including avoidance of antibiotic monotherapy, combination treatment with topical modalities, and limiting the duration of oral antibiotic use.

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Anti-acne drugs in phase 1 and 2 clinical trials. Zouboulis CC, Dessinioti C, Tsatsou F, Gollnick HPM. *Expert Opin Investig Drugs.* 2017 Jun 19:1-11. doi: 10.1080/13543784.2017.1337745. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28627277>

INTRODUCTION: Despite the impressive increase of knowledge on acne etiology accumulated during the last 20 years, few efforts have been overtaken to introduce new therapeutic regimens targeting the ideal treatment of acne. The increasing emergence of microbial resistance associated with antibiotics, teratogenicity, particularly associated with systemic isotretinoin, and the need for an adverse drug profile, which can be tolerated by the patient, make the need of new pathogenesis relevant anti-acne agents an emerging issue. Areas covered: A search for phase 1 and 2 acne treatment trials in the US National Institutes of Health database of clinical trials and the European Medicines Agency database with the key words 'acne' and 'treatment' was carried out, on 6 January 2017. Expert opinion: The detected trials mostly investigate topical agents that may act via sebosuppressive effects, antimicrobial properties or anti-inflammatory actions. The compounds under investigation include olumacostat, glasaretil, cortaxalone, 17 α -propionate, stearoyl-CoA desaturase 1 inhibitors, agents affecting the melanocortin system, omiganan, and minocycline. Systemic studied anti-acne drugs include finasteride, biologics, low dose anti-inflammatory antibiotics, and leukotriene B4 inhibitors.

Systemic therapy of ocular and cutaneous rosacea in children. Gonser LI, Gonser CE, Deuter C, et al. *J Eur Acad Dermatol Venereol.* 2017 Jun 16. doi: 10.1111/jdv.14402. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28621909>

BACKGROUND: In paediatric rosacea, ocular symptoms are often predominant. Literature about systemic therapy of paediatric ocular rosacea is sparse, though. OBJECTIVE: Analysis of children with ocular rosacea treated systemically, particularly addressing remission and recurrence rates. METHODS: Retrospective study reviewing the medical records of children with ocular rosacea treated with systemic antibiotic therapy. Nine out of 19 patients were chosen for detailed analysis. To our knowledge, this is the first study in paediatric ocular rosacea requiring systemic therapy with a larger patient group and a longer follow-up (mean follow-up = 30.2 months). RESULTS: Seventeen patients (89.5%) suffered from blepharitis, 15 patients (78.9%) from conjunctivitis, twelve patients (63.2%) from chalazia/styes and nine female patients (47.4%) from corneal involvement. We used erythromycin (n = 9) or roxithromycin (n = 1) in patients younger than eight years and doxycycline (n = 8) or minocycline (n = 1) in patients older than eight years. Seven out of nine patients treated with erythromycin, one out of eight patients treated with doxycycline and the patient treated with minocycline achieved a complete remission of ocular and cutaneous

symptoms. Two out of nine patients treated with erythromycin, seven out of eight patients treated with doxycycline and the patient treated with roxithromycin achieved a partial remission. Relapses occurred in the patient treated with minocycline (cutaneous), two out of eight patients treated with doxycycline (ocular and cutaneous) and one out of nine patients treated with erythromycin (cutaneous). **CONCLUSION:** To achieve a complete remission of cutaneous and ocular rosacea, a long-term anti-inflammatory treatment of at least six months is necessary. The remission and relapse rates after successful treatment seem to be lower than in adults as all nine patients treated with erythromycin achieved a complete remission and did not show any relapse. This article is protected by copyright. All rights reserved.

Sex- and Age-Adjusted Population Analysis of Prevalence Estimates for Hidradenitis Suppurativa in the United States. Garg A, Kirby JS, Lavian J, et al. *JAMA Dermatol.* 2017 May 10. doi: 10.1001/jamadermatol.2017.0201. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/28492923>

IMPORTANCE: The true prevalence of hidradenitis suppurativa (HS) is unknown. **OBJECTIVE:** To establish standardized overall and group-specific prevalence estimates for HS in the United States. **DESIGN, SETTING, AND PARTICIPANTS:** This retrospective analysis included a demographically heterogeneous population-based sample of more than 48 million unique patients across all US census regions. As of October 27, 2016, a total of 47 690 patients with HS were identified using electronic health record data. **MAIN OUTCOMES AND MEASURES:** Standardized overall point prevalence for HS and sex-, age-, and race-specific prevalence estimates of HS in the general US population. **RESULTS:** Of the 47 690 patients with HS (26.2% men and 73.8% women), the overall HS prevalence in the US population sample was 0.10%, or 98 per 100 000 persons (95% CI, 97-99 per 100 000 persons). The adjusted prevalence in women was 137 per 100 000 (95% CI, 136-139 per 100 000), more than twice that of men (58 per 100 000; 95% CI, 57-59 per 100 000; $P < .001$). The prevalence of HS was highest among patients aged 30 to 39 years (172 per 100 000; 95% CI, 169-275 per 100 000) compared with all other age groups (range, 15-150 per 100 000; $P < .001$). Adjusted HS prevalences among African American (296 per 100 000; 95% CI, 291-300 per 100 000) and biracial (218 per 100 000; 95% CI, 202-235 per 100 000) patients were more than 3-fold and 2-fold greater, respectively, than that among white patients (95 per 100 000; 95% CI, 94-96 per 100 000; $P < .001$). **CONCLUSIONS AND RELEVANCE:** Hidradenitis suppurativa is an uncommon, but not rare, disease in the United States that disproportionately affects female patients, young adults, and African American and biracial patients.

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Patient Counseling/Communication

Pollution and acne: is there a link? Krutmann J, Moyal D, Liu W, et al. *Clin Cosmet Investig Dermatol.* 2017 May 19;10:199-204. doi: 10.2147/CCID.S131323. eCollection 2017. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5446966/>

In recent years, the critical role that inflammation may play in the development and progression of acne has become increasingly recognized. The prevalence of acne is similar between Asian and Caucasian women, but Asian women have a higher prevalence of inflammatory acne. They also report their symptoms exacerbate during periods of high air pollution. The objective of this study was to review the current evidence that links air pollution to worsening of

acne symptoms. Firstly, a group of five Asian and three European scientists with expertise in Dermatology reviewed the current literature and described current acne treatment practices in their countries. During this activity, they identified the need for further epidemiological and clinical research. Secondly, additional studies ensued which provided evidence that acne symptoms might exacerbate in regions of high ambient air pollution. Based on these findings, the authors suggest that people with acne should protect the natural barrier function of their skin with emollients and ultraviolet (UV)A/UVB protection.

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Isotretinoin for Acne: Tips for Prescribing and Managing Patient Concerns. Stephen P. Stone, MD Cutis. 2017 June;99(6):378, 388 <http://www.mdedge.com/cutis/article/139719/acne/isotretinoin-acne-tips-prescribing-and-managing-patient-concerns?channel=171>

What does your patient need to know at the first visit? Most important is what you need to know before the first visit. As the prescribing physician, you must be familiar with the iPLEDGE program. Because of the complexity of the program, consider identifying a physician in your area to refer patients if you are not going to be a regular prescriber of the medication. If you are enrolled in iPLEDGE, let your patients (and/or their parents/guardians) know that there is a great deal of misinformation on the Internet. Reiterate that you and your staff are available to discuss their concerns. Also, give them reliable sources of information, such as the American Academy of Dermatology's patient information sheet as well as the Mayo Clinic's acne information. Drugs.com is another resource. All patients—males, females who cannot become pregnant, and females of childbearing potential (FCBPs)—must be aware that this medication can cause birth defects if taken during pregnancy. They must be informed that the medication is not to be shared with anyone and that they should not give blood while taking this medication.

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