

One Step Closer to the Holy Grail of Acne Care

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The United States is experiencing an acne epidemic. Up to 95 percent of adolescents suffer from the condition and more than 50 percent of people over the age of 25 still deal with some degree of acne. It is the nation's most common skin condition.

Despite the widespread prevalence, the standard of care for acne has not changed much in 40 years. Many over-the-counter and prescription options exist for moderate-to-severe acne. Dermatologists prescribe alternating cycles of an oral antibiotic, like tetracycline, doxycycline, and minocycline, that target *P. acnes*, the bacteria that causes acne, and a topical treatment that contains benzoyl peroxide or retinoids.

This combination treatment offers good results for some, but there is a growing need for safer, more effective strategies. Oral antibiotics often bring side effects, like dizziness, nausea, and diarrhea. Because of prolonged use, they could lead to antibiotic resistance. Topical treatments are typically less effective and have other side effects, including skin irritation and flaking.

Acne patients may soon have another option, which some doctors call the "holy grail" of acne care: a truly safe and effective topical therapy. A phase 2b clinical trial studied a promising topical gel formulation of the antibiotic minocycline (BPX-01 by BioPharmX Corporation). It formulates the leading acne antibiotic, minocycline, into a unique, hydrophilic topical gel.

The gel is non-oily and non-staining and leaves no residue. It has demonstrated high penetration and targeted delivery of minocycline directly through the skin at the site where acne develops. It has both antibacterial and



anti-inflammatory properties and a lower resistance rate than other antibiotics. By combining the efficacy of an antibiotic, the benefits of targeted application through topical delivery, and by minimizing the side effects associated with both, this topical gel promises to be a new safe and effective option for the millions of people with moderate-to-severe acne.

This gel also works. Research showed the two percent minocycline formulation reduced the number of inflammatory lesions in acne patients by 59 percent (versus 44 percent for the vehicle), with no serious drug-related adverse side effects experienced.

Additionally, findings suggest it may also lessen the severity of lesions. The phase 2b study measured reduc-

tion in a five point investigator's global assessment (IGA) scale and among 25 percent of the subjects treated with BPX-01, two percent showed at least a two-grade improvement and an IGA of clear or almost clear.

BPX-01 promises to be at least as effective in reducing acne lesions as the most effective topical products currently available on the market, but without their side effects. Furthermore, the drug holds the promise of being a complete alternative to oral antibiotics. Research found no traceable levels of minocycline in patients' plasma, an enormous advantage over oral minocycline.

BioPharmX expects to launch phase three clinical trials for BPX-01 soon, so no product will be available commercially for at least another two years.