



## Xepi™ (ozenoxacin) – New drug approval

- On December 11, 2017, the [FDA approved](#) Ferrer Internacional's [Xepi \(ozenoxacin\)](#), for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older.
- Ozenoxacin is a quinolone antimicrobial drug that has activity against *S. aureus* and *S. pyogenes* infections.
- The safety and efficacy of Xepi were demonstrated in two placebo-controlled studies of 723 patients with impetigo. Overall clinical success was defined as no need for additional antimicrobial therapy and absence/reduction in clinical signs and symptoms assessed at the end of therapy (day 6 - 7).
  - In study 1, clinical success was significantly better in Xepi-treated patients vs. placebo-treated patients (34.8% vs. 19.2%,  $p = 0.002$ ).
  - In study 2, clinical success was significantly better in Xepi-treated patients vs. placebo-treated patients (54.4% vs. 37.9%,  $p = 0.001$ ).
- Warnings and precautions of Xepi include potential for microbial overgrowth.
- The most common adverse reactions (reported in 1 patient) of Xepi use were rosacea and seborrheic dermatitis.
- The recommended dosage of Xepi is to apply a thin layer topically to the affected area twice daily for five days.
  - Affected area may be up to 100 cm<sup>2</sup> in adult and pediatric patients  $\geq 12$  years of age or 2% of the total body surface area and not exceeding 100 cm<sup>2</sup> in pediatric patients  $< 12$  years of age.
- Ferrer Internacional's launch plans for Xepi are pending. Xepi will be available as 1% cream.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](http://optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.