Generic Name:
Ozenoxacin cream, 1%
Trade Name:
Xepi
Company:
Medimetriks Pharmaceuticals
Notes:

FDA approved ozenoxacin cream, 1%, for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients aged 2 months and older. The new chemical entity, applied topically twice daily for 5 days, belongs to a new generation of nonfluorinated quinolones.

In two Phase III pivotal studies, ozenoxacin cream showed positive efficacy and appeared to be safe and well tolerated in both adult and pediatric populations aged 2 months and older. It also demonstrated excellent in vitro antibacterial activity against pathologically relevant bacteria and clinical isolates of organisms with emerging resistance to methicillin-resistant *S. aureus* (MRSA).

Safety and effectiveness in pediatric patients younger than 2 months of age have not been established.

Medication Monitor Categories:
New Drug Approvals

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