



## **XEPI™ INDICATION AND IMPORTANT SAFETY INFORMATION**

### **INDICATIONS AND USAGE**

Xepi™ (ozenoxacin) Cream, 1% is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older. Affected area may be up to 100 cm<sup>2</sup> in adult and pediatric patients 12 years of age and older or 2% of the total body surface area and not exceeding 100 cm<sup>2</sup> in pediatric patients less than 12 years of age.

The safety and effectiveness of Xepi™ in pediatric patients younger than 2 months of age have not been established.

Xepi™ is for external use only. Not for oral, ophthalmic, intranasal, or intravaginal use.

### **IMPORTANT SAFETY INFORMATION**

#### **WARNINGS AND PRECAUTIONS**

Prolonged use of Xepi™ may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, discontinue use and institute alternative therapy.

#### **ADVERSE REACTIONS**

Adverse reactions (rosacea and seborrheic dermatitis) were reported in 1 adult patient treated with Xepi™. The safety profile of Xepi™ in pediatric patients 2 months and older was similar to that of adults.

**Please see accompanying full Prescribing Information for Xepi™.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.**