



(ozenoxacin) Cream, 1%

IT'S WHAT RESISTANT BACTERIA FEAR MOST



You want impetigo and the bacteria* causing it gone fast. Your doctor may prescribe Xepi® (ozenoxacin) Cream, 1%, **impetigo's worst nightmare.**¹⁻³

**Staphylococcus aureus* and *Streptococcus pyogenes*.
S. aureus; *S. pyogenes*

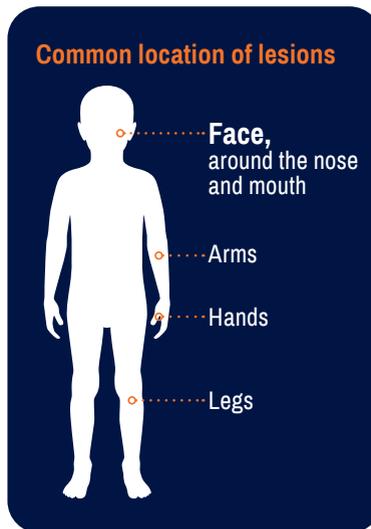
IMPORTANT SAFETY INFORMATION

Uses: Xepi® (ozenoxacin) Cream, 1% is a topical prescription medicine approved for the treatment of impetigo, a skin infection caused by the bacteria *Staphylococcus aureus* or *Streptococcus pyogenes*, and is approved for adults and children two months of age and older.

Please see Important Safety Information throughout.

WHAT IS IMPETIGO (IMPETIGINOUS BACTERIA*)?

- **Impetigo (im-puh-TIE-go) is a common and highly contagious bacterial skin infection.**⁴ It is caused by *Staphylococcus aureus* (STAFF-oh-low-cock-us ORE-ee-us), *Streptococcus pyogenes* (STREP-toe-cock-us PIE-oh-en-eez), or both⁵
- **Impetigo causes red, itchy sores.** The sores can be anywhere on the body but are most often found on exposed areas of skin, like on the face around the nose and mouth, hands, arms, and legs. These sores break open and leak a clear fluid for a few days. They then form a yellowish crust^{4,6}
- Although impetigo occurs mostly in children between the ages of 2 and 5 years, **people of any age can be affected**⁶



How do you get impetigo?

- **Impetigo is highly contagious** and can easily spread throughout a family or within groups that have close contact with each other^{4,6}
- Anyone with skin-to-skin contact, like parents and siblings, children in school, or people on sports teams, can spread impetigo with unwashed hands or with shared towels, sheets, clothing, toys, or other personal items^{4,6}

**S. aureus*; *S. pyogenes*

How do you keep impetigo from spreading?

- To help keep this bacterial infection from spreading to others, people with impetigo are advised to stay home from work or school until the infected sores have healed (dried) or until after at least 24 hours of antibiotic treatment^{4,6}

How do you treat impetigo?

- **An antibiotic treatment prescribed by your doctor can not only stop impetigo from spreading** to family and friends, it can also help impetigo go away faster⁵
- **If not treated, an impetigo infection could continue for 2 to 3 weeks**, which could affect your child's ability to go to school or daycare and your ability to go to work⁵
- **Cream or ointment antibiotics** are usually the treatment chosen first by doctors and will usually need to be used for 5 to 7 days^{1,5,7}



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Pregnancy Warning: There is no available data on Xepi® use in pregnant women to inform a drug associated risk.

Lactation Warning: There is no available data regarding the presence of the active ingredient (ozenoxacin) in human milk, or the effects of ozenoxacin on the breastfed infant or on milk production.

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IMPORTANT SAFETY INFORMATION (continued)

Most common side effects were:

- Rosacea (a skin condition that may include redness, flushing and acne-like lesions) and seborrheic dermatitis (a skin condition that causes scaly patches and red skin) were reported in 1 adult patient treated with Xepi®.



ABOUT XEPI® (ozenoxacin) CREAM, 1%

- Xepi® is an antibiotic cream that treats impetigo by killing *S. aureus* and *S. pyogenes* bacteria¹
- Antibiotics can be either bacteriostatic or bactericidal⁸
 - **Bacteriostatic** drugs slow bacterial growth but do not kill bacteria
 - **Bactericidal** drugs disrupt and kill bacteria cells



Xepi® has you covered because its active ingredient, ozenoxacin, is bactericidal and kills susceptible strains of *S. aureus* and *S. pyogenes* that cause impetigo⁹

- This includes activity against methicillin-resistant *S. aureus* (MRSA) in a laboratory setting¹

Xepi® works within days to get you back to normal life



- Clearance of impetiginous bacteria* was seen after 5 days of treatment twice a day^{2,3}
 - With substantial improvement as early as 2 to 3 days^{2,3}



Contact your dermatologist if your infection does not start to get better after 3 days.¹

**S. aureus*; *S. pyogenes*

IMPORTANT SAFETY INFORMATION (continued)

Directions:

- Use Xepi® for the entire time, as directed by your Health Care Provider.
- Do not use Xepi® if the affected area of impetigo is bigger than the size of the child's two (2) hands.
- Xepi® is for external use only.
- Do not swallow Xepi® or use in the eyes, on the mouth or lips, inside the nose, or inside the female genital area. Wash your hands after application if hands are not the area for treatment.

Please see Important Safety Information throughout.

Medical studies compared the effect of Xepi® and a placebo cream (cream without the active drug) on impetigo in patients with *S. aureus* and/or *S. pyogenes*¹⁻³

- Xepi® showed a significant improvement at the end of 5 days of therapy when compared to the placebo cream¹⁻³
- Xepi® was tested in 2 medical studies that included 723 people aged 2 months or older. Participants were randomly assigned to receive either Xepi® or the placebo cream and did not know which cream they were given (blinded)¹⁻³
- They applied Xepi® or the placebo twice a day for 5 days. The affected body surface could not be larger than 2% for patients aged 2 months to 11 years¹⁻³
- The percentage of patients with no more or fewer symptoms and not requiring additional antimicrobial therapy for the treated areas is shown in the table below, grouped according to the type of bacteria causing impetigo (*S. aureus* and/or *S. pyogenes*)¹

	STUDY 1 ¹		STUDY 2 ¹	
	Xepi® %	Placebo %	Xepi® %	Placebo %
<i>S. aureus</i>	37.6%	16.3%	57.4%	33.3%
<i>S. pyogenes</i>	39.7%	10.4%	78.9%	40%

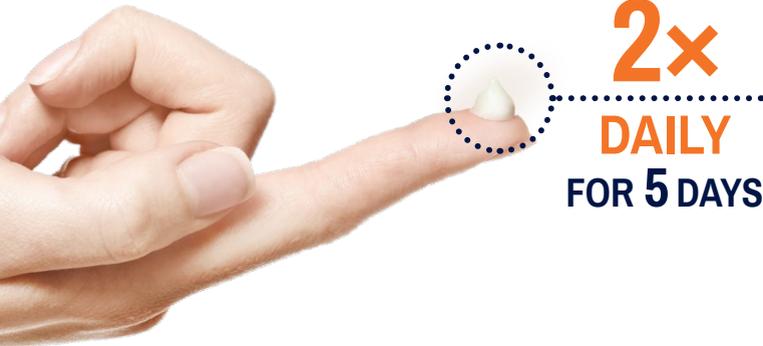
Most common side effects were:

- Rosacea (a skin condition that may include redness, flushing and acne-like lesions) and seborrheic dermatitis (a skin condition that causes scaly patches and red skin) were reported in 1 adult patient treated with Xepi®.

IMPORTANT SAFETY INFORMATION (continued)

- **Potential for Microbial Overgrowth:** The prolonged use of Xepi® may result in hard-to-treat bacteria and fungi. Notify your healthcare practitioner if there is no improvement in symptoms within 3 days after starting use of Xepi®.

HOW DO I USE XEPI[®] (ozenoxacin) CREAM, 1%?¹



2x
DAILY
FOR 5 DAYS

- Xepi[®] is a prescription drug approved for adults and children 2 months of age and older
- Wash your hands after applying Xepi[®] if hands are not the area being treated
- Apply Xepi[®] in a thin layer twice per day, for 5 days, where impetigo sores are present
- Do not use Xepi[®] if the affected area of impetigo is bigger than the size of the child's two (2) hands (100 cm²)
- Use Xepi[®] only on the skin. Don't apply Xepi[®] in your eyes or body cavities (like your mouth or nose)

Does Xepi[®] have any side effects?¹

- Xepi[®] was proven to be safe in studies of both adults and children 2 months of age and older
- Fewer than 1% of patients in clinical studies had side effects, which were:
 - Rosacea, which is a skin condition that may include redness, flushing, and acne-like lesions
 - Seborrheic dermatitis, which is a skin condition that causes scaly patches and red skin



IMPORTANT SAFETY INFORMATION (continued)

Pediatric Warning: The safety and effectiveness of Xepi[®] in the treatment of impetigo have been established in patients 2 months to 17 years of age. The safety profile of Xepi[®] in patients 2 months and older was similar to that of adults. The safety and effectiveness of Xepi[®] have not been established in patients younger than 2 months of age.

Please see Important Safety Information throughout.

IMPORTANT SAFETY INFORMATION (continued)

Geriatric Warning: Clinical studies of Xepi[®] did not include sufficient numbers of patients aged 65 and older to find out whether they respond differently from younger patients.

HOW DO I GET XEPI® (ozenoxacin) CREAM, 1%?

Your prescription for Xepi® will be sent to be fulfilled by a specialty pharmacy. Work with your doctor's office to determine if delivery to your home is available.



All commercially insured patients
pay \$35[†]



Xepi® is prescribed by your doctor, who sends the prescription to a specialty pharmacy.



Xepi® is fulfilled by a specialty pharmacy in your area.



Specialty pharmacy may deliver Xepi® directly to your door.



You can pick up Xepi® directly from the specialty pharmacy.

Once your doctor places the prescription, Xepi® should be ready within 2 days.

This offer is not valid if you are eligible for reimbursement of this product in whole or part under Medicare, Medicaid, Medigap, VA, DOD or government-subsidized clinics or similar federal or state programs. Uninsured, cash paying patients are also not eligible to participate in the Biofrontera Patient Savings Program. Only patients with commercial insurance are eligible to participate in the Biofrontera Patient Savings Program to reduce out-of-pocket expenses on eligible prescriptions of Xepi® at participating pharmacies in the United States. This offer is limited to one time per patient in any 30-day period. This offer cannot be combined with any other offer. This offer is void where prohibited by law. Biofrontera reserves the right to rescind, revoke, or amend this offer at any time, without notice.

Patient Instructions: Eligible patients purchasing Xepi® with a valid prescription at participating pharmacies in the United States are automatically entitled to participate in the Biofrontera Patient Savings Program. Commercially-insured patients will pay as little as \$35 per prescription for up to 4 prescription fills per year of Xepi® (containing one 30g tube). Maximum benefit limits apply. Any remaining out-of-pocket costs will be the patient's responsibility. By utilizing this program, patient acknowledges and agrees to comply with the terms and conditions as set forth above.

[†]Excludes all state taxes and applicable fees; maximum benefits apply.

IMPORTANT SAFETY INFORMATION (continued)

Directions:

- Use Xepi® for the entire time, as directed by your Health Care Provider.
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Please see Important Safety Information throughout.

IMPORTANT SAFETY INFORMATION (continued)

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Most common side effects were:

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Inactive Ingredients: benzoic acid, octyldodecanol, peglicol 5 oleate, pegoxol 7 stearate, propylene glycol, purified water, stearyl alcohol

Other Information:

- **The risk information provided here is not comprehensive. To learn more, talk about Xepi[®] with your health care provider. The FDA approved product labeling can be found at <https://www.xepicream.com/PI>.**
- **You are encouraged to report side effects of Xepi[®]. Please contact Biofrontera Inc. at 1-844-829-7434 or FDA at 1-800-332-1088 or www.fda.gov/medwatch.**

References: 1. Xepi[®] [package insert]. Woburn, MA: Biofrontera, Inc.; 2020. 2. Gropper S, Albareda N, Chelius K, et al. Ozenoxacin 1% cream in the treatment of impetigo: a multicenter, randomized, placebo- and retapamulin-controlled clinical trial. *Future Microbiol.* 2014;9(9):1013-1023. 3. Rosen T, Albareda N, Rosenberg N, et al. Efficacy and safety of ozenoxacin cream for treatment of adult and pediatric patients with impetigo: a randomized clinical trial. *JAMA Dermatol.* 2018;154(7):806-813. 4. Impetigo. Mayo Clinic. Accessed June 10, 2021. <https://www.mayoclinic.org/diseases-conditions/impetigo/symptoms-causes/syc-20352352>. 5. Hartman-Adams H, Banvard C, Juckett G. Impetigo: diagnosis and treatment. *Am Fam Physician.* 2014;90(4):229-235. 6. Impetigo: all you need to know, Centers for Disease Control and Prevention. Accessed June 10, 2021. <https://www.cdc.gov/groupastrep/diseases-public/impetigo.html>. 7. Pereira LB. Impetigo review. *An Bras Dermatol.* 2014;89(2):293-299. 8. Leeka S, Terrell CL, Edson RS. General principles of antimicrobial therapy. *Mayo Clin Proc.* 2011;86(2):156-167. 9. Canton R, Morrissey I, Vila J, et al. Comparative in vitro antibacterial activity of ozenoxacin against Gram-positive clinical isolates. *Future Microbiol.* 2018;13:3-19.



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Concerned about impetigo? Talk to your dermatologist about Xepi[®].

ALL COMMERCIALY INSURED PATIENTS PAY \$35[†]
Visit xepicream.com for more information.

**S. aureus*; *S. pyogenes*

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120 Presidential Way, Suite 330, Woburn, MA 01801
customer_service@biofrontera.com | biofrontera.us.com | XEP-US023V001

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