

PATIENT INFORMATION

**ZILXI® (ZILK-see)
(minocycline)
topical foam**

Important Information: ZILXI is for use on the skin only (topical use). ZILXI is not for use in your mouth, eyes, or vagina.

What is ZILXI?

ZILXI is a prescription medicine used on the skin (topical) to treat adults with pimples and bumps caused by a condition called rosacea.

ZILXI should not be used for the treatment of infections.

It is not known if ZILXI is safe and effective in children.

Do not use ZILXI if you are allergic to any tetracycline medicines or to any of the ingredients in ZILXI. Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Before using ZILXI, tell your healthcare provider about all of your medical conditions, including if you:

- have diarrhea or watery stools
- have liver problems
- have kidney problems
- are pregnant or plan to become pregnant. Taking tetracycline medicines by mouth during pregnancy may cause serious side effects on the growth of bone and teeth of your baby. ZILXI topical foam is used on your skin and it is not known if it will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with ZILXI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements, and skin products you use. Tetracycline medicines taken by mouth may affect the way other medicines work and may increase your chance of developing certain side effects.

Especially tell your healthcare provider if you take:

- a blood thinner medicine
- a penicillin antibiotic medicine
- isotretinoin

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

How should I use ZILXI?

- See the detailed “**Instructions for Use**” included with this leaflet for directions about how to apply ZILXI the right way.
- Use ZILXI exactly as your healthcare provider tells you.
- Apply ZILXI to your entire face at about the same time each day, at least 1 hour before bedtime. You should apply enough ZILXI to cover the entire face.
- Do not bathe, shower, or swim for at least 1 hour after applying ZILXI.
- Wash your hands after applying ZILXI.

What should I avoid while using ZILXI?

- ZILXI is flammable. Avoid fire, flames, and smoking when applying and right after you apply ZILXI.
- Limit your time in sunlight. Avoid sunlight or artificial sunlight such as sunlamps or tanning beds. Use sun protection measures such as sunscreen and wear loose-fitting clothes that cover your skin while out in sunlight. Stop using ZILXI if you get sunburn.
- Minocycline taken by mouth may cause feelings of light-headedness, dizziness, or spinning (vertigo). You should not drive or operate dangerous machinery if you have these symptoms during treatment with ZILXI.

What are possible side effects of ZILXI?

ZILXI contains minocycline, a tetracycline medicine. Tetracyclines, when taken by mouth, may cause serious side effects, including:

- **Harm to an unborn baby.** See “**What should I tell my healthcare provider before using ZILXI?**”

- **Permanent tooth discoloration.** Tetracycline medicine when taken by mouth may permanently turn a baby or child's teeth yellow-gray-brown during tooth development. You should not use ZILXI during tooth development. Tooth development happens in the second and third trimesters of pregnancy, and from birth up to 8 years of age.
- **Slow bone growth.** Tetracycline medicine taken by mouth may slow bone growth in infants and children. Slow bone growth is reversible after stopping treatment.
- **Diarrhea.** Diarrhea can happen with most antibiotics, including minocycline taken by mouth. This diarrhea may be caused by an infection (*Clostridioides difficile*) in your intestines. Call your healthcare provider right away if you get watery or bloody stools while using ZILXI.
- **Liver problems.** Minocycline taken by mouth can cause serious liver problems that may lead to death. Stop using ZILXI and call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:
 - loss of appetite
 - tiredness
 - diarrhea
 - yellowing of your skin or the white of your eyes (jaundice)
 - bleeding more easily than normal
 - confusion
 - sleepiness
- **Central nervous system effects.** See “What should I avoid while using ZILXI?”
- **Increased pressure in the brain (intracranial hypertension).** This condition may lead to vision changes and permanent vision loss. You are more likely to get intracranial hypertension if you are a female of childbearing potential and are overweight or have a history of intracranial hypertension. Stop using ZILXI and tell your healthcare provider right away if you have blurred vision, double vision, vision loss, or unusual headaches.
- **Immune system reactions including a lupus-like syndrome, hepatitis, and inflammation of blood or lymph vessels (vasculitis)** have happened during treatment with minocycline taken by mouth. Call your healthcare provider right away if you get a fever, rash, joint pain, or body weakness.
- **Sensitivity to sunlight (photosensitivity).** See “What should I avoid while using ZILXI?”
- **Serious skin or allergic reactions** have happened during treatment with minocycline taken by mouth that may affect parts of your body such as your liver, lungs, kidneys and heart. Sometimes these can lead to death. Stop using ZILXI and go to the nearest hospital emergency room right away if you have any of the following signs or symptoms:
 - skin rash, hives, sores in your mouth, or your skin blisters and peels
 - swelling of your face, eyes, lips, tongue, or throat
 - trouble swallowing or breathing
 - blood in your urine
 - fever, yellowing of the skin or the whites of your eyes (jaundice), dark colored urine
 - pain on the right side of the stomach area (abdominal pain)
 - chest pain or abnormal heartbeats
 - swelling in your legs, ankles, and feet
- **Discoloration (hyperpigmentation).** Minocycline taken by mouth may cause darkening of your skin, scars, teeth, or gums.

The most common side effect of ZILXI is diarrhea.

Your healthcare provider may stop your treatment with ZILXI if you develop certain side effects.

These are not all the possible side effects with ZILXI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZILXI?

- Store ZILXI at room temperature below 77°F (25°C) for 90 days.
- Do not store ZILXI in the refrigerator.
- Do not puncture or burn the ZILXI can.
- Do not expose to heat or temperatures above 120°F (49°C)

Keep ZILXI and all medicines out of the reach of children.

General information about the safe and effective use of ZILXI.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflet. Do not use ZILXI for a condition for which it was not prescribed. Do not give ZILXI to other people, even if they have the same

symptoms you have. It may harm them. You can also ask your healthcare provider or pharmacist for information about ZILXI that is written for health professionals.

What are the ingredients in ZILXI?

Active ingredient: minocycline

Inactive ingredients: soybean oil, coconut oil, light mineral oil, cyclomethicone, cetostearyl alcohol, stearic acid, myristyl alcohol, hydrogenated castor oil, white wax (beeswax), stearyl alcohol, docosanol . ZILXI is dispensed from an aluminum container (can) pressurized with propellant (butane + isobutane + propane).

Manufactured by: ASM Aerosol-Service AG, Mohlin, Switzerland
Manufactured for: VYNE Pharmaceuticals Inc., Bridgewater, NJ 08807
Product of Portugal or Switzerland

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For more information, go to www.ZILXI.com or call VYNE Pharmaceuticals Inc. at 1-844-375-3673.

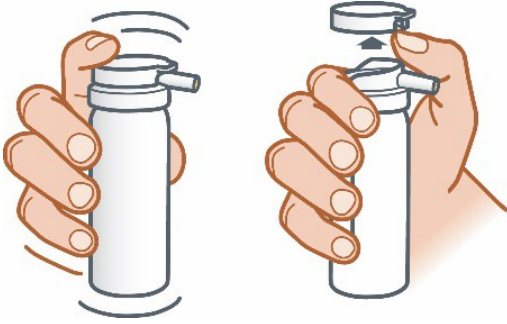

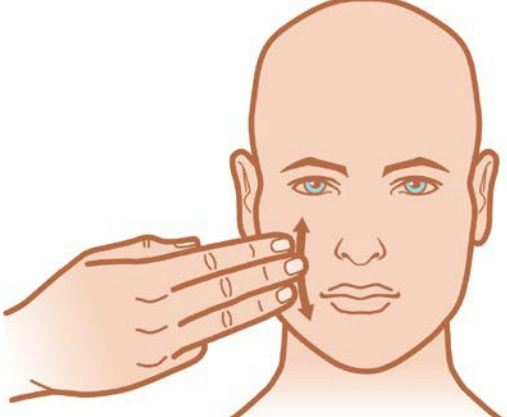
INSTRUCTIONS FOR USE
ZILXI® (ZILK-see)
(minocycline)
topical foam

Important Information: ZILXI is for use on skin only (topical use). ZILXI is not for use in your mouth, eyes or vagina.

Read this Instructions for Use before you start using ZILXI and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. Use ZILXI exactly as your healthcare provider tells you.

Before applying ZILXI:

- When using a new ZILXI can, wait until the can has warmed to room temperature before use.
- If necessary, wash your face gently with a mild non-medicated cleanser, rinse with water, and pat your skin dry.
- Apply ZILXI to your entire face at about the same time each day, at least 1 hour before bedtime.

<p>Step 1: Shake the can well. Place thumb under tab above nozzle and lift up to remove the cap from the ZILXI can.</p>	 An illustration showing two hands holding a white cylindrical can. The left hand is shaking the can, indicated by curved motion lines. The right hand is lifting the cap off the nozzle.
<p>Step 2: Press the top of the can to dispense a small amount (cherry-sized amount) of ZILXI onto your fingertips.</p>	 An illustration showing a hand holding the can and pressing the top. The foam is being dispensed onto the fingertips of the other hand.
<p>Step 3: Apply a thin layer of ZILXI and gently rub onto your entire face. You may need to use additional ZILXI to make sure that your entire face is treated.</p>	 An illustration of a person's face. A hand is shown applying the foam to the cheek, with arrows indicating the direction of application.
<ul style="list-style-type: none">• Wash your hands after applying ZILXI.• ZILXI can stain fabric.	

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