

**PATIENT INFORMATION**

**AMZEEQ® (am-Zeek)  
(minocycline)  
topical foam**

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

**What is AMZEEQ?**

AMZEEQ is a prescription medicine used on the skin (topical) for the treatment of pimples and red bumps (non-nodular inflammatory lesions) that happen with moderate to severe acne vulgaris in adults and children 9 years of age and older.

AMZEEQ should not be used for the treatment of infections.

It is not known if AMZEEQ is safe and effective in children under 9 years of age.

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

**What should I tell my healthcare provider before using AMZEEQ?**

**Before using AMZEEQ, 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. AMZEEQ 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 AMZEEQ.

**Tell your healthcare provider about all the other medicines you take**, including prescription and over-the-counter medicines, vitamins and herbal supplements. Tetracycline medicines taken by mouth may affect the way other medicines work, and may increase your risk of 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 AMZEEQ?**

- See the detailed **“Instructions for Use”** included with this leaflet for directions about how to apply AMZEEQ the right way.
- Use AMZEEQ exactly as your healthcare provider tells you.
- Apply AMZEEQ to the affected skin area(s) at about the same time each day, at least 1 hour before bedtime.
- Do not bathe, shower, or swim for at least 1 hour after applying AMZEEQ.
- Wash your hands after applying AMZEEQ.

**What should I avoid while using AMZEEQ?**

- AMZEEQ is flammable. Avoid fire, flame, and smoking when applying and right after you apply AMZEEQ.
- 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 AMZEEQ 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 AMZEEQ.

**What are possible side effects of AMZEEQ?**

**AMZEEQ 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 AMZEEQ?”**
- **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 AMZEEQ 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 AMZEEQ.
- **Liver problems.** Minocycline taken by mouth to treat acne can cause serious liver problems that may lead to death. Stop using AMZEEQ 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 AMZEEQ?”
- **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 AMZEEQ 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 AMZEEQ?”
- **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 AMZEEQ 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 AMZEEQ is headache.**

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

These are not all the possible side effects with AMZEEQ.

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 AMZEEQ?**

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

**Keep AMZEEQ and all medicines out of the reach of children.**

#### **General information about the safe and effective use of AMZEEQ.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use AMZEEQ for a condition for which it was not prescribed. Do not give AMZEEQ to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about AMZEEQ that is written for health professionals.

**What are the ingredients in AMZEEQ?**

**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 and 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.AMZEEQ.com](http://www.AMZEEQ.com) or call VYNE Pharmaceuticals Inc. at 1-844-375-3673.

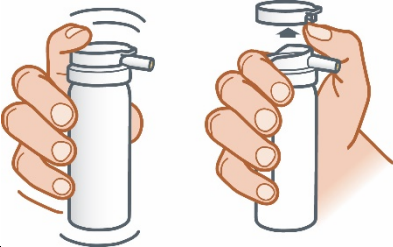

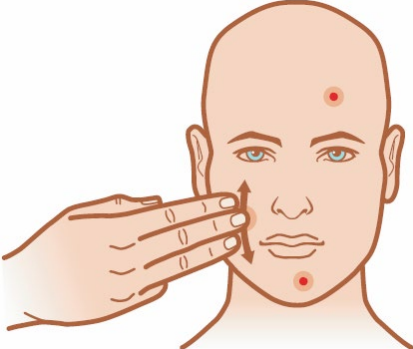
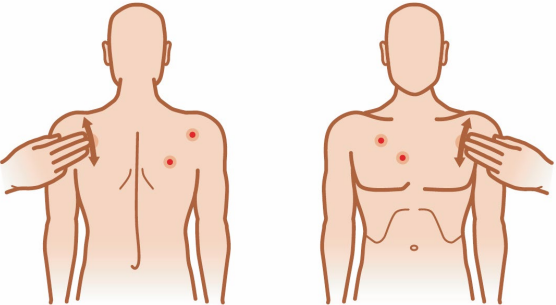
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**AMZEEQ® (am-Zeek)**  
**(minocycline)**  
**topical foam**

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Read this Instructions for Use before you start using AMZEEQ 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 AMZEEQ exactly as your healthcare provider tells you.

**Before applying AMZEEQ:**

- Allow the AMZEEQ can to warm to room temperature before first use.
- Wash your face gently with mild cleanser, rinse with water, and pat your skin dry.

	<p><b>Step 1:</b> Shake the can well. Place thumb under tab above nozzle and lift up to remove the cap from the AMZEEQ foam can.</p>
	<p><b>Step 2:</b> Press the top of the can to dispense a small amount of AMZEEQ foam onto your fingertips.</p>
	<p><b>Step 3:</b> Apply and gently rub AMZEEQ foam into the affected areas.</p>
	<p><b>Step 4:</b> If acne is present on other parts of your body (neck, shoulders, arms, back or chest), additional amounts of AMZEEQ foam should also be applied to these affected areas as directed by your healthcare provider.</p>
<ul style="list-style-type: none"><li>• Wash your hands after applying AMZEEQ.</li><li>• AMZEEQ can stain fabric.</li></ul>	

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