

# ACNE WANTS AFIGHT? BRINGSTON.

**AMZEEQ** is a prescription medicine used on the skin for the treatment of pimples and red bumps that may occur with moderate to severe acne in people 9 years of age and older.

See Limitations of Use on the following page.



# WE'RE HERE TO HELP YOU FIGHT YOUR MODERATE TO SEVERE ACNE

Meet AMZEEQ, a product that may help you in your fight against the pimples and red bumps that may occur with moderate to severe acne in people 9 years of age and older. Whether it shows up before a test, a birthday, an interview, a date, or for no reason at all, consider yourself ready to battle acne and the inflammation that comes with it.

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#### **LIMITATIONS OF USE**

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

Please see additional Important Safety Information on page 15 and throughout.

# WHAT IS ACNE?



You may be wondering why acne chose you.

Well, you're not alone—over 85% of teens and young adults in the US have struggled with acne at some point. Of that, 10 million have battled moderate to severe acne, a condition where you have anywhere from 20 to 100 pimples at any aiven time.

First and foremost, where does acne come from?

Acne is caused by clogged pores and inflammation that stem from natural oil production and the increased bacteria that result from it. Acne can be inflammatory, which are usually painful, red pimples underneath the skin.

NO MATTER HOW AGNE
APPEARS, IT CAN BE
ANNOYING AND AFFECT YOUR
LIFE—BUT ONCE YOU'VE HAD
ENOUGH, YOU CAN CHOOSE
TO FIGHT BACK

# DEBUNKING AGNE MYTHS

# WHAT IS AMZEEQ?





# MYTH YOU'RE NOT WASHING OR BATHING ENOUGH

#### FACT

Overwashing your face can cause irritation and imbalances in oil production that can actually worsen acne, and even keep treatment from working as it should.



# MYTH ADDING OIL TO SKIN WILL MAKE THINGS WORSE

#### FACT

While oilier skin can lead to more acne, there are many benefits to using natural oils on your skin. Some of these include repairing skin barrier damage, antibacterial and anti-inflammatory effects, as well as the potential to heal wounds and fight aging.



#### MYTH YOU SHOULD GET MORE SUN

#### FACT

Though getting a tan may help lessen the appearance of acne, it doesn't actually cure it. In fact, it can increase signs of aging. Many acne treatments actually increase your sensitivity to the sun, so be sure to talk to your doctor about how this may affect your treatment plan.



## MYTH YOUR DIET IS THE PROBLEM

#### FACT

There have been many studies on acne triggers but most of the ones involving food—like dairy or chocolate—have little proof that diet actually causes acne.



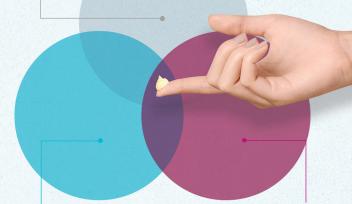
#### PRODUCTS SHOULD WORK RIGHT AWAY

#### FACT

It can feel like if something doesn't work in a few weeks that it's not right for you, but some treatments may provide their best benefit after 3, or even 4, months. Though you may start to see treatments working after a few weeks, continuing to use the treatment as your doctor prescribed will help get you closer to your treatment goals. Stick with it.

# The power of an antibiotic

AMZEEQ contains minocycline, an antibiotic that's been used for almost 50 years AN ALLY IN THE FIGHT AGAINST AGNE\*



# Contains naturally moisturizing ingredients

AMZEEQ contains soybean and coconut oils that are naturally moisturizing,<sup>†</sup> and is paraben and sulfate free<sup>‡</sup>

# The innovation of a foam

Minocycline has never been available for use directly on the skin, and having it in a foam makes it easy to use. Just a small amount spreads easily and is gentle on skin

‡The clinical relevance of this is unknown.

#### IMPORTANT SAFETY INFORMATION

 Do not use AMZEEQ if you are allergic to AMZEEQ or any tetracycline medicine. Stop using AMZEEQ right away and call your doctor if you get a rash or other allergic symptom.

<sup>\*</sup>For the pimples and red bumps that may occur with moderate to severe acne in people 9 years of age and older.

<sup>†</sup>AMZEEQ contains the following 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.

# HOW CAN AMZEEQ HELP?



We know what it takes to tackle acne head-on. AMZEEQ significantly reduced pimples and red bumps by week 12

In scientific studies, people using AMZEEQ had a

43% - 54%

(VS 34%-42% WITH PLACEBO FOAM)\*

#### reduction in pimples and red bumps

\*Trial design: Three 12-week, randomized, double-blind, vehicle-controlled trials in subjects 9 years and older with moderate to severe acne. A total of 1,357 subjects were treated with AMZEEQ and 1,061 with placebo foam that did not contain minocycline, the active ingredient.

We also know you want to fight acne with a low risk of side effects or skin irritation

#### Most common side effects

The most common side effect in clinical studies was headache, which happened in 3% of people.

# Most people did not experience skin irritation while using AMZEEQ

Doctors evaluated people's skin for signs and symptoms of redness, dryness, discoloration, itching and peeling after using AMZEEQ for 12 weeks:

- About 14% had mild signs and symptoms
- About 3% had moderate signs and symptoms
- 0.1% or less had severe signs and symptoms

We even asked how much people liked it, just to make sure it's something that people want to use, no matter how excited we are about it<sup>†</sup>



of people were satisfied with how easy AMZEEQ was to use



of people were satisfied with the overall product experience

In a survey of almost 1,000 people using AMZEEQ or placebo foam, people were asked about their level of satisfaction on a scale of 1 (very dissatisfied) to 5 (very satisfied) after 12 weeks. Satisfied = very satisfied + satisfied. This was not a scientific study and the importance of results is unknown.

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

 Before using AMZEEQ, tell your doctor about all of your medical conditions and the medicines you take. Do not use AMZEEQ if you are pregnant, may become pregnant or are nursing. If you become pregnant while using AMZEEQ, talk to your doctor. Tetracycline medicine when taken by mouth during pregnancy, infancy and/or childhood up to the age of 8 years may permanently discolor teeth (yellow-gray-brown) and may slow the growth of bones.

## HOW DO I USE AMZEEQ?





#### STEP 1:

#### CLEANSE

Gently wash your face and affected areas with a mild cleanser, or whatever cleanser your doctor may have recommended, rinse with water, and pat (don't rub!) your skin dry



#### STEP 2:

#### SHAKE

Shake the can well. Place thumb under tab above nozzle and lift up to remove the cap from the AMZEEQ can



#### STEP 3:

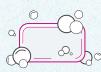
#### PRESS

Press the top of the can to dispense only a small amount of AMZEEQ onto your fingertips. You only need enough to cover the affected areas of the skin, so start small and use more if needed



# STEP 4: APPLY

Apply and gently rub into the affected areas. If you have acne on your neck, shoulders, arms, back, or chest, additional amounts of foam may be applied to these areas, too (but don't forget to use a small amount—a little goes a long way!)



#### STEP 5

#### WASH

Wash hands immediately after you're finished applying AMZEEQ

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

- AMZEEQ is flammable. Avoid fire, flame, and smoking when applying and right after you apply AMZEEQ.
- Protect your skin from the sun while using AMZEEQ. Avoid sunlight or artificial sunlight such as sunlamps or tanning beds. Stop using AMZEEQ if you get a sunburn.

# AMZEEQ only needs to be applied once a day. But before you get started:

- If using a new AMZEEQ can, allow it to warm to room temperature before first use. The can is then stored at room temperature for future use
- · Use AMZEEQ exactly as your doctor tells you
- Apply AMZEEQ at approximately the same time each day
  - If before bed, make sure you do your routine at least 1 hour before going to sleep
  - Do not bathe, shower, or swim for at least 1 hour after application of the product

#### Yellowing may occur with AMZEEQ

A mild, temporary "glare" may occur on the skin. Don't worry! This is not staining of the skin and will wash off with soap and water. You should wait at least 1 hour to wash your skin after applying AMZEEQ. If you notice stains on your fabrics, use cold water to wash them out.



WATCH OUR STEP-BY-STEP
INSTRUCTION VIDEO BY
VISITING <u>AMZEEQ.COM/IFU</u>
OR SCANNING THE QR CODE
ON THIS PAGE

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

 When taken by mouth, minocycline may cause feelings of lightheadedness, dizziness or spinning. You should not drive or operate dangerous machinery if you have these symptoms.

# EXTRA SUPPORT





It's okay to feel like you don't know everything—you're just getting started

#### **Online AMZEEQ resources**

We have a number of online resources that can help you start and stay on track with AMZEEQ, including:





ACNE MYTHS & FACTS



**SAVINGS CARD** 

VISIT <u>AMZEEQ.COM</u> TO ACCESS
THESE RESOURCES, PATIENT
INFORMATION, AND MORE

#### You can learn more about acne

Don't hesitate to reach out to the experts! The American Academy of Dermatology (<a href="www.acad.org">www.acad.org</a>) or the American Acne and Rosacea Society (<a href="www.acneandrosacea.org">www.acneandrosacea.org</a>) websites can help you navigate your treatment journey.

# Getting acne under control requires teamwork

As your child (9 years and older) ages, it may be hard to make sure they're taken care of. They may want to keep to themselves, but they still value your opinion, no matter what they say (or don't say). We know you're as much in the fight against acne as they are. **We're here to help with that.** 

#### Here are some quick tips that can help you keep their acne at bay:

- Help them get the most out of their treatment by making sure they're using their AMZEEQ as prescribed
- Maintain low stress levels by taking care of the basics—make sure your child is getting enough sleep and drinking enough water
- Keep follow-up appointments so you and their doctor can track their progress and keep them motivated to stay on treatment
- It's easy to put your child's needs ahead of your own, but don't forget to take care of yourself—you'll help them more when you help yourself first

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

AMZEEQ is a topical foam that contains minocycline, a tetracycline medicine. It is not taken by mouth. However, tetracyclines, when taken by mouth (capsules or tablets), may cause serious side effects, including: diarrhea which may be caused by an infection and can cause watery or bloody stools; loss of appetite; tiredness; yellowing of your skin or eyes (jaundice); bleeding more easily than normal; confusion; sleepiness; vision changes, including blurred vision, double vision, or permanent vision loss; unusual headaches; fever; rash; joint pain; body weakness; discoloration or darkening of your skin, scars, teeth, or gums. Call your doctor right away if these side effects occur.

# TALKING TO YOUR DOCTOR



Doctor Discussion Guide  Having a better relationship with your doctor can improve the way you feel about treatment and can provide answers to questions you have.	Here's some space to write in any other questions or notes you may have:
Some questions that you may want to ask your doctor:	
HOW SEVERE IS MY ACNE?	
• WHEN WILL I SEE IMPROVEMENT?	
HOW LONG WILL I HAVE TO BE ON TREATMENT?	
IS AMZEEQ RIGHT FOR ME?	
WHAT SHOULD MY SKIN CARE ROUTINE BE?	
WHAT SHOULD I LOOK FOR WHEN BUYING SKIN CARE PRODUCTS OR MAKEUP?	
DO ANY OF MY OTHER MEDICATIONS AFFECT MY ACNE?	
IMPORTANT SAFETY INFORMATION (CONTINUED) The most common side effect of AMZEEQ is headache.	
These are not all of the possible side effects with AMZEEQ. Call your	

and throughout.

doctor for medical advice about side effects.

Please see additional Important Safety Information on page 15

# SAVE ON AMZEEQ



#### The AMZEEQ Savings Card

# Commercially insured, eligible\* patients may be able to save money on an AMZEEQ prescription with the AMZEEQ Savings Card

- If you're commercially insured, you could pay as little as \$35
- If you are commercially insured and your insurance doesn't cover AMZEEQ, you could still pay as little as \$95



# DOWNLOAD YOUR CARD BY TEXTING AMZEEQ TO 66580 OR VISITING AMZEEQ.COM/SAVINGS†

# WANT TO KNOW EXACTLY HOW MUCH YOUR COPAY WILL BE? USE THE TRUCHECK™ TOOL ON AMZEEQ.COM/SAVINGS AND FIND OUT

#### \*Additional Eligibility Criteria & Terms:

This copay card is not valid for use by patients who are covered by any federal or state funded healthcare program (including, but not limited to, Medicare [Part D and Medigap], Medicaid, any state pharmaceutical assistance program, TRICARE, VA, or DoD). Offer good only in the U.S., including Puerto Rico. This card is good for use only with a valid AMZEEQ prescription at the time the prescription is filled by the pharmacist and dispensed to the patient. Void where prohibited by law, taxed, or restricted. This offer cannot be combined with any other promotional offer. Cost may vary based on pharmacy. For full details, visit AMZEEQ.com/savings.

†Message and data rates may apply.

#### INDICATION

AMZEEQ is a prescription medicine used on the skin (topical) for the treatment of pimples and red bumps (non-nodular inflammatory lesions) of moderate to severe acne in patients 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. AMZEEQ is for use on skin only (topical use). AMZEEQ is not for use in your mouth, eyes or vagina.

#### IMPORTANT SAFETY INFORMATION

- Do not use AMZEEQ if you are allergic to AMZEEQ or any tetracycline medicine. Stop using AMZEEQ right away and call your doctor if you get a rash or other allergic symptom.
- Before using AMZEEQ, tell your doctor about all of your medical conditions and the medicines you take. Do not use AMZEEQ if you are pregnant, may become pregnant or are nursing. If you become pregnant while using AMZEEQ, talk to your doctor. Tetracycline medicine when taken by mouth during pregnancy, infancy and/or childhood up to the age of 8 years may permanently discolor teeth (yellow-gray-brown) and may slow the growth of bones.
- AMZEEQ is flammable. Avoid fire, flame, and smoking when applying and right after you apply AMZEEQ.
- Protect your skin from the sun while using AMZEEQ. Avoid sunlight or artificial sunlight such as sunlamps or tanning beds. Stop using AMZEEQ if you get a sunburn.
- When taken by mouth, minocycline may cause feelings of lightheadedness, dizziness or spinning. You should not drive or operate dangerous machinery if you have these symptoms.

AMZEEQ is a topical foam that contains minocycline, a tetracycline medicine. It is not taken by mouth. However, tetracyclines, when taken by mouth (capsules or tablets), may cause serious side effects, including: diarrhea which may be caused by an infection and can cause watery or bloody stools; loss of appetite; tiredness; yellowing of your skin or eyes (jaundice); bleeding more easily than normal; confusion; sleepiness; vision changes, including blurred vision, double vision, or permanent vision loss; unusual headaches; fever; rash; joint pain; body weakness; discoloration or darkening of your skin, scars, teeth, or gums. Call your doctor right away if these side effects occur.

The most common side effect of AMZEEQ is headache.

These are not all of the possible side effects with AMZEEQ. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

Please see accompanying Patient Information and Instructions for Use.

# HERES TO FIGHTING TOGETHIER

For resources, more information, and to register for updates on all things AMZEEQ, visit AMZEEQ.com

Please see Important Safety Information on page 15 and throughout.







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COM-AMZ-US-210063 05/2021

#### 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
  - o tiredness
  - diarrhea
  - yellowing of your skin or the white of your eyes (jaundice)
- bleeding more easily than normal
- confusion
- o 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
  - o swelling of your face, eyes, lips, tongue, or throat
  - trouble swallowing or breathing
  - o blood in your urine
  - fever, yellowing of the skin or the whites of your eyes (jaundice), dark colored urine
  - o 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 or call VYNE Pharmaceuticals Inc. at 1-844-375-3673.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 01/2021

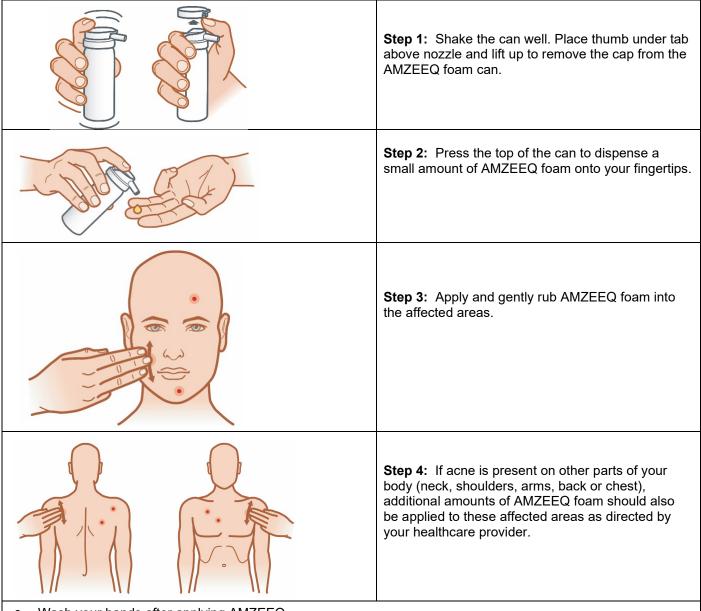
#### INSTRUCTIONS FOR USE AMZEEQ® (am-Zeek) (minocycline) topical foam

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

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.



- Wash your hands after applying AMZEEQ.
- AMZEEQ can stain fabric.

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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