Qutenza®
(capsaicin) 8% topical system

In-office treatment guide for QUTENZA[1]

For adult patients with painful diabetic peripheral neuropathy (PDPN) of the feet or postherpetic neuralgia (PHN)

1 Patient information

Counsel your patients on administration

Before application, review all potential side effects with your patients. Explain that a topical analgesic will be applied prior to the application, and an analgesic and/or cold pack could be used during or following application, including at home.

Visit QUTENZA.com/hcp to watch a video on how to prepare for QUTENZA application.

Think about the following for your patients' application:

- Suggest patients bring reading material
- Recommend patients with painful DPN bring socks
- Remind patients that some areas may be sensitive following application. Driving or operating a vehicle may be uncomfortable

2 Before application

Suggested supplies

- Blood pressure device
- Nitrile (not latex) gloves
- Face masks
- Access to water and basin to cleanse the skin
- Soft towel to dry the skin
- Topical anesthetic
- Tongue depressor to apply anesthetic and cotton tip to locate area of allodynia
- Skin marker to mark painful area
- Biomedical waste container
- Gauze/medical tape
- Socks (for PDPN patients)
- Cool pack/ice pack
- Medical grade scissors
- Small manicure scissors
- **IMPORTANT:** Timer to track 30-minute application for PDPN of the feet or a 60-minute application for PHN

3 Post-application reminders

- It is important to schedule a **QUTENZA application every 3 months, or as warranted by the return of pain** (not more frequently than every 3 months)
- Dispose of all treatment materials as described
- Inform the patient that the treated area may be sensitive to heat for a few days (eg, hot showers/baths, direct sunlight, vigorous exercise)

Remind your patients to schedule their 3-month application appointment before leaving the office.

INDICATION

QUTENZA® (capsaicin) 8% topical system is indicated in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and for neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Only physicians or healthcare professionals under the close supervision of a physician are to administer and handle QUTENZA.

Unintended exposure to capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin in healthcare providers and others. When administering QUTENZA, it is important to follow these procedures:

- Administer QUTENZA in a well-ventilated treatment area.

Please see additional Important Safety Information on next page. Please see full Prescribing Information.

Qutenza®
(capsaicin) 8% topical system

Make QUTENZA your first add-on treatment for adult patients with PDPN of the feet or PHN


Not actual patients.

IMPORTANT SAFETY INFORMATION (cont)

- Wear only nitrile gloves when handling QUTENZA or any item that makes contact with QUTENZA, and when cleaning capsaicin residue from the skin. Do not use latex gloves as they do not provide adequate protection.
- Use of a face mask and protective glasses is advisable for healthcare providers.
- Keep QUTENZA in the sealed pouch until immediately before use.
- Use QUTENZA only on dry, intact (unbroken) skin.
- In patients treated for neuropathic pain associated with diabetic peripheral neuropathy, a careful examination of the feet should be undertaken prior to each application of QUTENZA to detect skin lesions related to underlying neuropathy or vascular insufficiency.
- During administration, avoid unnecessary contact with any items in the room, including items that the patient may later have contact with, such as horizontal surfaces and bedsheets.
- Aerosolization of capsaicin can occur upon rapid removal of QUTENZA. Therefore, remove QUTENZA gently and slowly by rolling the adhesive side inward.
- Immediately after use, clean all areas that had contact with QUTENZA and properly dispose of QUTENZA, associated packaging, Cleansing Gel, gloves, and other treatment materials in accordance with local biomedical waste procedures.
- If QUTENZA is cut, ensure unused pieces are properly disposed of.

Contraindications

None

Warnings and Precautions

- Unintended exposure to capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin.
- Do not apply QUTENZA to the face, eyes, mouth, nose, or scalp to avoid risk of exposure to eyes or mucous membranes. Accidental exposure to the eyes and mucous membranes can occur from touching QUTENZA or items exposed to capsaicin and then touching the eyes and mucous membranes. Wear nitrile gloves when administering QUTENZA and avoid unnecessary contact with items in the room, including items that the patient may later have contact with, such as horizontal surfaces and bedsheets. If irritation of eyes or mucous membranes occurs, remove the affected individual from the vicinity of QUTENZA and flush eyes and mucous membranes with cool water.
- Aerosolization of capsaicin can occur upon rapid removal of QUTENZA. Therefore, remove QUTENZA gently and slowly by rolling the adhesive side inward. Inhalation of airborne capsaicin can result in coughing or sneezing. If irritation of airways occurs, remove the affected individual from the vicinity of QUTENZA. Provide supportive medical care if shortness of breath develops.
- If skin not intended to be treated is exposed to QUTENZA, apply Cleansing Gel for one minute and wipe off with dry gauze. After the Cleansing Gel has been wiped off, wash the area with soap and water.
- Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following the application procedure with local cooling (such as a cold pack) and/or appropriate analgesic medication.
- Transient increases in blood pressure may occur during and shortly after the QUTENZA treatment. Blood pressure changes were associated with treatment-related increases in pain. Monitor blood pressure and provide adequate support for treatment-related pain. Patients with unstable or poorly controlled hypertension, or a recent history of cardiovascular or cerebrovascular events, may be at an increased risk of adverse cardiovascular effects. Consider these factors prior to initiating QUTENZA treatment.
- Reductions in sensory function have been reported following administration of QUTENZA. Decreases in sensory function are generally minor and temporary. All patients with pre-existing sensory deficits should be clinically assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory deterioration or loss is detected or pre-existing sensory deficit worsens, continued use of QUTENZA treatment should be reconsidered.

Adverse Reactions

In all controlled clinical trials, adverse reactions occurring in ≥5% of patients in the QUTENZA group and at an incidence at least 1% greater than in the control group were application site erythema, application site pain, and application site pruritus.

Adverse Event Reporting

Physicians, other healthcare providers, and patients are encouraged to voluntarily report adverse events involving drugs or medical devices. To make a report you can:

- In the U.S., visit www.fda.gov/medwatch or call 1-800-FDA-1088; or
- For QUTENZA, you may also call 1-877-900-6479 and select option 1, or press zero on your keypad to talk to an operator to direct your call.

Please see full Prescribing Information.

REFERENCE: 1. QUTENZA® [prescribing information]. Morristown, NJ: Averitas Pharma, Inc.

AveritasPharma™

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