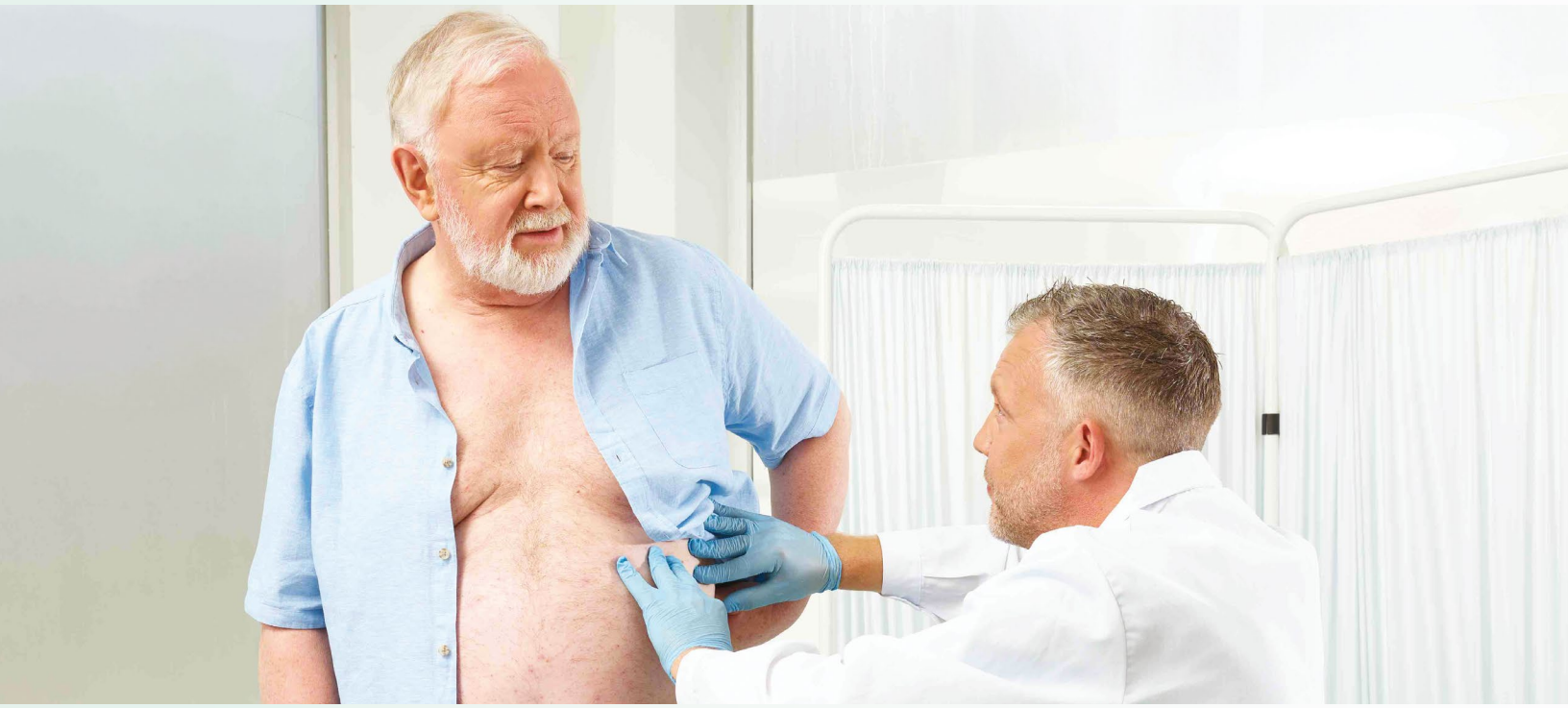
Qutenza®
(capsaicin) 8% topical system

QUTENZA APPLICATION GUIDE

for neuropathic pain associated with postherpetic neuralgia (PHN)



INDICATION

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

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Use only on dry, unbroken skin. Only physicians or healthcare professionals are to administer and handle QUTENZA, following the procedures in the label.

Please see Important Safety Information on page 4 and full Prescribing Information.

In-office treatment guide for QUTENZA

For adult patients with postherpetic neuralgia (PHN)

PREPARE YOUR PATIENTS

- Discuss expectations from treatment
- Review potential side effects
- Inform patients that a topical anesthetic or cooling pack (from a refrigerator) may be used to relieve discomfort associated with the application of QUTENZA
- Suggest that patients bring reading material for their 60-minute application

SUGGESTED SUPPLIES

- QUTENZA kit (topical system(s) and post-application Cleansing Gel)
- Blood pressure device
- Nitrile (not latex) gloves
- Face masks
- Access to water and basin to cleanse the skin
- Soft towel to dry the skin
- Skin marker to mark painful area
- Biomedical waste container
- Self-adhesive bandage/gauze
- Cooling pack (from a refrigerator)
- Medical grade scissors
- Timer to track 60-minute application for painful PHN

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).
- Inform the patient that the treated area may be sensitive to heat for a few days (eg, hot showers/baths, direct sunlight, vigorous exercise).

For ongoing pain relief, schedule your patient's next appointment when they leave.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Severe Irritation:** Whether applied directly or transferred accidentally from other surfaces, capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin to the healthcare professional, patients, and others. Do not use near eyes or mucous membranes, including face and scalp. Take protective measures, including wearing nitrile gloves and not touching items or surfaces that the patient may also touch. Flush irritated mucous membranes or eyes with water and provide supportive medical care for shortness of breath. Remove affected individuals from the vicinity of QUTENZA. Do not re-expose affected individuals to QUTENZA if respiratory irritation worsens or does not resolve. If skin not intended to be treated comes into contact with QUTENZA, apply Cleansing Gel and then wipe off with dry gauze. Thoroughly clean all areas and items exposed to QUTENZA and dispose of properly. Because aerosolization of capsaicin can occur with rapid removal, administer QUTENZA in a well-ventilated area, and remove gently and slowly, rolling the adhesive side inward.

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Treatment steps for QUTENZA[1]

Qutenza® (capsaicin) 8% topical system

1. IDENTIFY

- The treatment area must be identified and marked on the skin with skin marker.
- Examine the area prior to application of QUTENZA to detect skin lesions related to underlying neuropathy or vascular insufficiency.
- If necessary, clip hair (do not shave) in and around the identified treatment area to promote QUTENZA adherence.
- QUTENZA can be cut to match the size and shape of the treatment area. Gently wash the treatment area with mild soap and water, and dry thoroughly.
- While not required, a topical anesthetic may be used at your discretion, based on clinical assessment of patient symptoms, before treatment with QUTENZA.

Note: Do not use the post-application QUTENZA Cleansing Gel until after the application. Administer QUTENZA in a well-ventilated treatment area. Put on nitrile (not latex) gloves.* Use of a face mask and protective glasses is recommended. Inspect the pouch. Do not use if the pouch has been torn or damaged.

2. APPLY

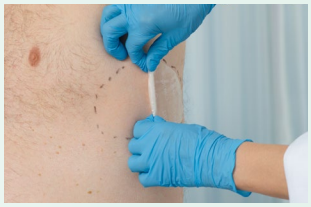
- Check blood pressure during and following the treatment.
- Tear open the pouch along the 3 dashed lines and remove QUTENZA .
- Inspect the outer surface backing layer with the printing on one side and the capsaicin-containing adhesive on the other side. The adhesive side is covered by a clear, unprinted, diagonally cut release liner.
- Cut QUTENZA before removing the protective release liner. Properly dispose of unused portions.
- The diagonal cut in the release liner is to aid in its removal. Peel a small section of the release liner back and place the adhesive side of QUTENZA on the treatment area.

***Latex or vinyl gloves do not provide enough protection from the active ingredient, capsaicin.**

2. APPLY (cont)

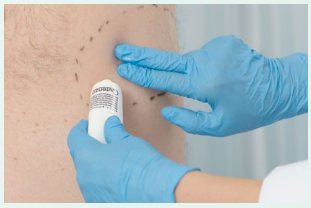
- While you slowly peel back the release liner with one hand, use the other hand to smooth QUTENZA down onto the skin.
- **Once QUTENZA is applied, leave in place for 60 minutes**
- Press QUTENZA firmly in place, as the silicone adhesive is pressure sensitive, and secure the topical system using either rolled gauze or a self-adhesive wrap to maintain constant contact with the treatment area.
- Instruct the patient not to touch QUTENZA or the treatment area.
- Cooling packs (from a refrigerator) may be placed on the treatment area during or post treatment to alleviate any temporary discomfort.

3. REMOVE



- Put on nitrile (not latex) gloves. Remove QUTENZA by gently and slowly rolling inward to prevent aerosolization of capsaicin, which can occur upon rapid removal of QUTENZA.

4. CLEANSE



- After removal of QUTENZA, liberally apply the post-application QUTENZA Cleansing Gel to the treatment area to ensure any residual capsaicin is removed. Leave on for at least 1 minute. Remove the post-application QUTENZA Cleansing Gel with a dry wipe and gently wash the area with mild soap and water. Dry thoroughly.
- Place the used QUTENZA, associated packaging, post-application QUTENZA Cleansing Gel, gloves, and other treatment materials in a biohazard bag and dispose of properly. If you do not have access to a biohazard bag, dispose of the used QUTENZA in the trash and completely tie the bag to avoid any unintended exposure or contamination.
- Inform the patient that the treated area may be sensitive for a few days to heat (eg, hot showers/baths, direct sunlight, vigorous exercise).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Severe Application Site Burns:** Full-thickness (third-degree) and deep partial-thickness (second-degree) burns have been reported following administration of QUTENZA. Cases of full-thickness (third-degree) burns, requiring hospitalization and skin grafting have been reported in patients who received QUTENZA for an unapproved indication and/or frequency of dosing at an application site where there had been prior skin trauma. Ensure that dosage and administration recommendations are followed.

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QUTENZA—Designed to be different

TREATS PAIN DIFFERENTLY: First and only noninvasive, in-office treatment that locally targets the root of neuropathic pain, temporarily reducing nerve fibers.[2-6]

SUSTAINED RELIEF MEASURED IN MONTHS, NOT DAYS: In a clinical study of adult PHN patients, QUTENZA delivered up to 3 months of sustained pain relief with each 60-minute, in-office treatment.[1,7]

ESTABLISHED SAFETY PROFILE: Topical nonopioid treatment has a low risk of systemic side effects, no known drug-drug interactions, and can be used alone or in combination with standard of care (SoC).[1]

References: 1. Averitas Pharma I. Qutenza® (capsaicin) topical system: US prescribing information. https:// www.qutenza.com/pdfs/Qutenza_Prescribing_Information.pdf. **2.** Schreiber AK, Nones CF, Reis RC, et al. Diabetic neuropathic pain: physiopathology and treatment. *World J Diabetes*. 2015;6(3):432-444. **3.** Biotechnology Information. PubChem Patent Summary for US-8821920-B2: Therapeutic patch for transdermal delivery of capsaicin. PubChem website. https://pubchem. ncbi.nlm.nih.gov/patent/US-8821920-B2. Accessed March 17, 2023. **4.** Wohlrab J, Neubert RH, Heskamp ML, et al. Cutaneous drug delivery of capsaicin after in vitro administration of the 8% capsaicin dermal patch system. *Skin Pharmacol Physiol*. 2015;28(2):65-74. **5.** Peppin JF, Pappagallo M. Capsaicinoids in the treatment of neuropathic pain: a review. *Ther Adv Neurol Disord*. 2014;7(1):22-32. **6.** Yang H, Sloan G, Ye Y, et al. New perspective in diabetic neuropathy: from the periphery to the brain, a call for early detection, and precision medicine. *Front Endocrinol* (Lausanne). 2020;10:929. **7.** Simpson DM, Robinson-Papp J, Van J, et al. Capsaicin 8% patch in painful diabetic peripheral neuropathy: a randomized, double-blind, placebo-controlled study. *J Pain*. 2017;18(1):42-53.

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- **Application-Associated Pain:** Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following application with local cooling and/or appropriate analgesic medication.
- **Increase in Blood Pressure:** Transient increases in blood pressure may occur with QUTENZA treatment. Monitor blood pressure during and following treatment procedure and provide 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.
- **Sensory Function:** Reductions in sensory function (generally minor and temporary) have been reported following administration of QUTENZA. Assess for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory loss occurs, treatment should be reconsidered.
- **Severe Application Site Burns:** Full-thickness (third-degree) and deep partial-thickness (second-degree) burns have been reported following administration of QUTENZA. Cases of full-thickness (third-degree) burns, requiring hospitalization and skin grafting have been reported in patients who received QUTENZA for an unapproved indication and/or frequency of dosing at an application site where there had been prior skin trauma. Ensure that dosage and administration recommendations are followed.

Adverse Reactions

The most common adverse reactions (≥5% and > control group) in all controlled clinical trials are application site erythema, application site pain, and application site pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Averitas Pharma, Inc. at 1-877-900-6479 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

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QZA-01-23-0015 v5.0 September 2024

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