

**Qutenza**<sup>®</sup>  
(capsaicin) 8% topical system

A hand is shown holding a translucent, adhesive patch over the top of a foot. The patch is printed with the text "capsaicin 8%" in a repeating pattern. The background features diagonal stripes in shades of purple, green, and blue.

# ADMINISTERING QUTENZA

## FOR PAINFUL DIABETIC PERIPHERAL NEUROPATHY (DPN) OF THE FEET

### INDICATION

QUTENZA<sup>®</sup> (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](#) throughout.  
Please see full [Prescribing Information](#).

# In-office treatment guide for QUTENZA

For adult patients with painful diabetic peripheral neuropathy (DPN) of the feet

## 1 PATIENT INFORMATION

### Counsel your patients on administration

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

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

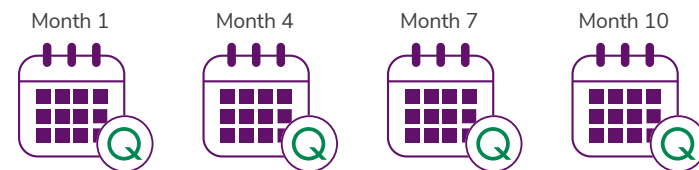
- Blood pressure device
- Nitrile (not latex) gloves
- Face masks
- Access to water and basin to cleanse the skin
- Soft towel to dry the skin
- Skin marker to mark painful area

- Biomedical waste container
- Gauze/medical tape
- Socks (for painful DPN patients)
- Cool pack/ice pack
- Medical grade scissors

**IMPORTANT:** Timer to track 30-minute application for painful DPN of the feet

## 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)



For ongoing pain relief, remind your patients that QUTENZA is therapy that is applied every 3 months and to schedule their 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.

Please see additional Important Safety Information throughout.

# Treatment steps for QUTENZA<sup>1</sup>

## STEP 1. PREPARE

- 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

## STEP 2. IDENTIFY

- The treatment area must be identified and marked on the skin
- Examine the feet 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 before treatment with QUTENZA



## STEP 3. APPLY QUTENZA

- Tear open the pouch along the three 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



## STEP 3. APPLY QUTENZA (cont)

- While you slowly peel back the release liner with one hand, use your other hand to smooth QUTENZA down onto the skin
- QUTENZA can be wrapped around the dorsal, lateral, and plantar surfaces of each foot to completely cover the treatment area
- **Once QUTENZA is applied, leave in place for 30 minutes on the feet (DPN)**
- To ensure QUTENZA maintains contact with the treatment area, a dressing, such as rolled gauze, may be used. Remove the nitrile gloves after the application
- Instruct the patient not to touch QUTENZA or the treatment area

## STEP 4. REMOVE QUTENZA

- 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



## STEP 5. CLEANSE

- After removal of QUTENZA, generously apply Cleansing Gel to the treatment area and leave on for at least one minute. Remove Cleansing Gel with a dry wipe and gently wash the area with mild soap and water. Dry thoroughly
- Properly dispose of QUTENZA, associated packaging, Cleansing Gel, gloves, and other treatment materials
- 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 Irritation (cont):** 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.

# QUTENZA – the unique matrix technology and high-concentration capsaicin may deliver significant and sustained pain relief in just 4 treatments a year<sup>1-4</sup>



## Sustained efficacy

Patients may experience up to 3 months of pain relief<sup>1</sup>



## Non-systemic, non-opioid, no drug-drug interactions



## Localized MOA



## Favorable safety profile

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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 (e.g., ice pack) 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. All patients with sensory deficits should be assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory loss occurs, treatment should be reconsidered.

#### Adverse Reactions

The most common adverse reactions ( $\geq 5\%$  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](http://www.fda.gov/medwatch).

Please see full [Prescribing Information](#).

**References:** 1. QUTENZA® [prescribing information]. Morristown, NJ: Averitas® Pharma, Inc. 2. National Center for 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 January 25, 2023. 3. Anand P, Privitera R, Donatien P, et al. Reversing painful and non-painful diabetic neuropathy with the capsaicin 8% patch: clinical evidence for pain relief and restoration of function via nerve fiber regeneration. *Front Neurol.* 2022;13:998904. 4. 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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