Qutenza® (capsaicin) 8% patch

Administration of the QUTENZA patch for painful diabetic peripheral neuropathy of the feet[1]

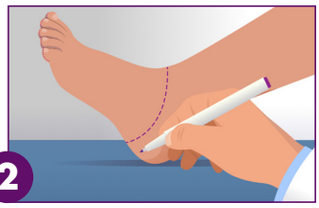
PREPARE

1

Administer QUTENZA in a well-ventilated treatment area.

Put on nitrile (not latex) gloves. Use of a face mask and protective glasses is advisable for healthcare providers.

Inspect the pouch. Do not use if the pouch has been torn or damaged.



2

IDENTIFY

The treatment area (painful area including areas of hypersensitivity and allodynia) must be identified by a physician or healthcare professional 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 patch 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.

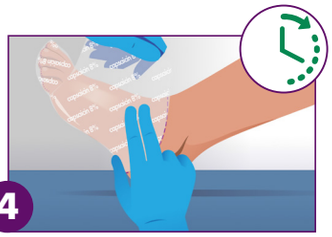
3

ANESTHETIZE

Pre-treat with a topical anesthetic to reduce discomfort associated with the application of QUTENZA.

Apply topical anesthetic to the entire treatment area and surrounding 1 to 2 cm, and keep the local anesthetic in place until the skin is anesthetized prior to the application of QUTENZA.

Remove the topical anesthetic with a dry wipe. Gently wash the treatment area with mild soap and water, and dry thoroughly.



4

APPLY

Tear open the pouch along the three dashed lines and remove the QUTENZA patch.

Inspect the QUTENZA patch and identify the outer surface backing layer with the printing on one side and the capsaicin-containing adhesive on the other side. The adhesive side of QUTENZA is covered by a clear, unprinted, diagonally cut release liner.

Cut QUTENZA before removing the protective release liner. Ensure the unused pieces do not make contact with other objects and are disposed of appropriately.

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.

While you slowly peel back the release liner from under the QUTENZA with one hand, use your other hand to smooth QUTENZA down onto the skin.

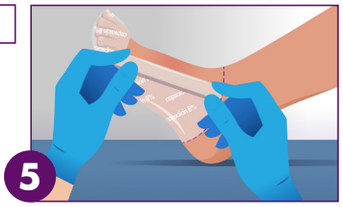
APPLY (continued)

QUTENZA patches 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.

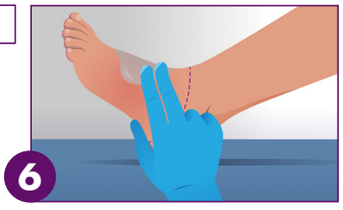
Instruct the patient not to touch QUTENZA or the treatment area.



5

REMOVE

Put on nitrile (not latex) gloves. Remove QUTENZA by gently and slowly rolling inward.



6

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.

Dispose of all treatment materials as described.

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

The recommended dose of QUTENZA **on the feet** is a single, **30-minute** application of up to 4 patches.

Approximate size of painful area (cm²)	# of patches needed
0–280	1
281–560	2
561–840	3
841–1120	4

Each patch is 14 cm x 20 cm (280 cm²).

Treatment with QUTENZA may be repeated every 3 months or as warranted by the return of pain (not more frequently than every 3 months).

Please see Important Safety Information on reverse.

Qutenza® (capsaicin) 8% patch

Watch a demonstration video of how QUTENZA is applied to the feet for PDPN:

INDICATION

QUTENZA® (capsaicin) 8% patch 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.
- 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 accompanying full Prescribing Information.

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

AveritasPharma™

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