

Treatment Guide

Qutenza® (capsaicin) 8% patch



QUTENZA® (capsaicin) 8% patch is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

Gather These Supplies

- Cotton-tipped applicators
- Skin marking pens
- Tracing paper or other similar paper such as exam table paper
- Topical anesthetic
- Several pairs of nitrile gloves (latex gloves do not provide adequate protection)
- Scissors
- Rolled gauze bandages
- Biohazard bag/container
- Mild soap
- Dry wipes
- QUTENZA patch(es) and Cleansing Gel

Counsel Your Patient

Patients may experience the following side effects, as observed in patients (≥5% and greater than control) in clinical studies:

- Localized skin redness or irritation
- Localized pain or burning sensation
- Localized itching
- Papules in the area of treatment
- Nausea
- Transient increase in blood pressure
- Sensitivity to heat (e.g., hot shower/bath, direct sunlight, vigorous exercise) for a few days

Advise patient:

- To notify you if they are pregnant or breastfeeding
- Not to touch the patch
- To inform you immediately if any of the side effects become severe or irritation of the eyes or airways occurs
- That medications given to treat acute pain during/after QUTENZA treatment, such as opioids, may affect the ability to perform potentially hazardous activities (e.g., driving or operating machinery)

IMPORTANT SAFETY INFORMATION:

Only physicians or healthcare professionals under the close supervision of a physician are to administer QUTENZA.

Please see additional Important Safety Information on page 3.

Prepare for Treatment

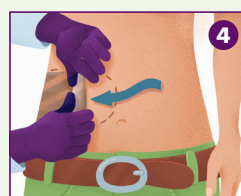
- Only physicians or healthcare professionals under the close supervision of a physician are to administer QUTENZA patch
- Monitor blood pressure during and following the treatment procedure
- Nitrile gloves must be worn when handling, applying, and cleaning capsaicin residue from the skin. Do not use latex gloves as they do not provide adequate protection
- It is advisable to administer QUTENZA in a well-ventilated treatment area, and to use a face mask and protective glasses
- Inspect the QUTENZA pouch. Do not use if the pouch has been torn or damaged
- Use QUTENZA only on dry, intact (unbroken) skin
- Prepare to treat acute pain during and following the procedure with local cooling and/or appropriate analgesics

Application Procedure



Identify

Mark painful areas (including areas of hypersensitivity and allodynia), clip hair (if necessary; do not shave), gently wash treatment area with mild soap and water, and dry thoroughly. **Treatment area must be identified by a physician.**



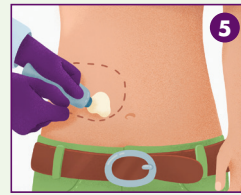
Remove

Remove patch by gently and slowly rolling it inward. Instruct patient not to touch the treatment area.



Anesthetize

Apply topical anesthetic to the entire treatment area and surrounding 1–2 cm. Keep anesthetic in place until the skin is anesthetized, then remove the topical anesthetic with a dry wipe. Gently wash the area with mild soap and water and dry thoroughly.



Cleanse

After removal of QUTENZA patch, generously apply Cleansing Gel to the treatment area and leave on for at least 1 minute. Remove Cleansing Gel with a dry wipe. Then gently wash the area with mild soap and water and dry thoroughly. Immediately after use, dispose of used and unused patches, Cleansing Gel, and other treatment materials in accordance with local biomedical waste procedures.



Apply

Before removing the protective release liner, cut QUTENZA to fit the treatment area, using the tracing paper, if necessary.

Apply the QUTENZA patch within 2 hours of opening the pouch. Peel back a small section of the release liner and place the adhesive side of the patch on the treatment area.

Slowly peel back the release liner from under

the patch while smoothing the patch down on to the treatment area. Leave in place for 60 minutes. A rolled gauze dressing may be used to ensure QUTENZA maintains contact with the treatment area.

The recommended dose of QUTENZA is a single, 60-minute application of up to 4 patches.

Approximate size of painful area (cm ²)	# 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).

IMPORTANT SAFETY INFORMATION (cont):

Contraindications:

None

Warnings and Precautions:

- Do not apply QUTENZA to the face or scalp to avoid risk of exposure to the eyes or mucous membranes.
- Aerosolization of capsaicin can occur and inhalation may result in coughing or sneezing.

Please see additional Important Safety Information on page 3.

Qutenza
(capsaicin) 8% patch

Indication:

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IMPORTANT SAFETY INFORMATION:

Only physicians or healthcare professionals under the close supervision of a physician are to administer QUTENZA.

Contraindications:

None

Warnings and Precautions:

- Do not apply QUTENZA to the face or scalp to avoid risk of exposure to the eyes or mucous membranes.
- Aerosolization of capsaicin can occur and inhalation may result in coughing or sneezing.
- If skin not intended to be treated comes into contact with QUTENZA, clean area using Cleansing Gel.
- Patients may experience substantial procedural pain. Prepare to treat pain 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.
- If opioids are used to treat pain associated with the application procedure, please note that opioid treatment may affect the patient's ability to perform potentially hazardous activities such as driving or operating heavy machinery.

Adverse Reactions:

In clinical trials, serious adverse reactions included application associated pain and increase in blood pressure. The most common adverse reactions ($\geq 5\%$ and greater than control) were application-site erythema, application-site pain, application-site pruritus, or application-site papules, and nausea.

To report an adverse event, you can visit www.fda.gov/medwatch or call 1-800-FDA-1088; or you can call Averitas Pharma, Inc. at 1-877-900-6479.

Please see accompanying full Prescribing Information.

www.QUTENZA.com



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M-QZA-US-10-19-0021 November 2019

