Qutenza® (capsaicin) 8% patch

Treatment Flow Sheet / Documentation Guide

Qutenza® is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

Please see Important Safety Information on last page.

Only physicians or health care professionals (HCP) under the close supervision of a physician are to administer Qutenza.

Patient Name: _____ Treatment Date: _____

Supervising Physician: _____

HCP applying Qutenza®: _____

Step 1 Identify

Identify the treatment area (painful area including areas of hypersensitivity and allodynia).
Record below:

Identify treatment area: _____ HCP Initials: _____

[Location, approximate size, etc.]

Dermal assessment: _____ HCP Initials: _____

[Skin should be dry and intact]

- If necessary, clip hair (do not shave) in and around the identified treatment area to promote patch adherence.
- Gently wash the treatment area with mild soap and water and dry thoroughly.
- Qutenza® can be cut to match the size and the shape of the treatment area.

Step 2 Anesthetize

Pre-treat with a topical anesthetic to reduce discomfort associated with patch application.

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

Optional recordings:

Anesthetic used: _____

Duration of anesthetic application: _____ : _____

In clinical trials, increases in blood pressure occurred during or shortly after exposure to Qutenza. Monitor blood pressure periodically during the treatment.

You may use the table below to record patient blood pressure prior, during, and post-treatment.

	Time	Blood Pressure^
Pre-treatment	:	
During treatment	:	
	:	
	:	
Prior to discharge	:	

^In clinical trials, increases in blood pressure occurred during or shortly after exposure to Qutenza®. Patients with unstable or poorly controlled hypertension, a recent history of cardiovascular or cerebrovascular events may be at an increased risk of adverse cardiovascular effects.

Step 3 Apply

Qutenza® patch application

***Important*: Wear nitrile gloves whenever handling patches.**

- Note the diagonal cut in the release liner; it is there to aid in patch application.
- Peel a small section of the release liner back, and place the adhesive side of the patch on the treatment area. NOTE: Ensure that skin is clean and dry.
- While you slowly peel back the release liner from under the patch with one hand, use your other hand to smooth the patch down on the patient's skin. Ensure tight adherence to the skin.
- To ensure Qutenza® maintains contact with the treatment area, a dressing such as rolled gauze may be used.
- Avoid patch overlap.

Record patches used in the table below:

Patch lot no.*	HCP initials

*Lot numbers are printed on the back of the foil pouch.
Dispose of all used and unused patch clippings in accordance with local biomedical waste procedures.

- After all patches are applied, record the application time: :
- Patches should be left in place for 60 minutes.
- Instruct the patient not to touch the patch or the treatment area.

Application-associated pain during and after patch application: Be prepared to treat acute pain during and following the application procedure if necessary with local cooling (such as a cold pack) and/or appropriate analgesic medication, such as opioids.

☐ **Yes, interventions required (use table below)**

☐ **No interventions required**

Record any interventions to manage treatment-associated discomfort below:

Time	Intervention*	Outcome (if aplicable)	HCP initials
:			
:			

*If analgesic medication(s) given, record drug, dose, and other pertinent information.

If treatment is prematurely terminated (< 60 minute patch removal) please complete table below:

Time	Est. time patch(es) in place	Reason for premature patch removal	HCP initials
:			

Step 4 Remove

***Important*: Wear nitrile gloves whenever handling patches.**

- Remove patches by gently and slowly rolling them inward.
- Immediately after use, dispose of used and unused patches, patch clippings, unused Cleansing Gel and associated treatment supplies in accordance with local biomedical waste procedures.

Step 5 Cleanse

- Cleanse treated area(s) immediately after treatment with Cleansing Gel provided in Qutenza® kit. Leave Cleansing Gel on the treatment area for at least 1 minute. Remove Cleansing Gel with a dry wipe.
- Gently wash treated 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 the local biomedical waste procedures.

Patch removal and cleansing completed by:

Time	HCP initials
:	

Patient Discharge

Patients can be discharged at the physician's discretion.

Inform patient that the treated area may be sensitive to heat and that they should avoid hot showers/bath, direct sunlight, or vigorous exercise for a few days following treatment.

Schedule follow-up visit, as necessary.

Time discharged/released:

Signature of provider(s):

IMPORTANT SAFETY INFORMATION

Indication
Qutenza® is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

Important Safety Information
Only physicians or healthcare professionals under the close supervision of a physician are to administer Qutenza.

Warnings and Precautions:

- Do not use on face or scalp.
- 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 pres sure 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

Adverse Reactions: In clinical trials, serious adverse reactions included application-associated pain and increase in blood pressure. The most common adverse reactions (≥ 5% and greater than control) were application-site erythema, application-site pain, application-site pruritus, or application-site papules, and nausea. These are not all the side effects of Qutenza. You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION.