

QUTENZA (capsaicin)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20,
2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Description: **Qutenza** is a single-use patch (14cm x 20cm) which contains 8% of a synthetic form of capsaicin (a substance found naturally in chili peppers). Capsaicin is an agonist for the transient receptor potential vanilloid 1 receptor (TRPV1), an ion channel-receptor complex expressed on nociceptive nerve fibers in the skin. Topical administration of capsaicin causes an initial enhanced stimulation of the TRPV1-expressing cutaneous nociceptors that may be associated with painful sensations followed by pain relief mediated by a reduction in TRPV1-expressing nociceptive nerve endings, a process that has been described as nociceptor defunctionalization.

Authorization:

Neuropathic pain: Management of neuropathic pain associated with postherpetic neuralgia and diabetic peripheral neuropathy of the feet in adults.

Muscle/Joint pain: Temporary relief of minor aches and pains of muscles and joints associated with simple backache, muscle strains, sprains, arthritis, bruises, or cramps, burning mouth syndrome.

NOTE: The following are unlabeled uses and not covered (see the VCHCP policy on Coverage of Prescription Medication for Off-Label use): diabetic neuropathy, treatment of pain associated with psoriasis and intractable pruritis.

Dosing:

Apply patch to most painful areas of the diabetic feet for 30 minutes or other neuropathic pain areas for 60 minutes. For muscle/joint pain apply 1 patch to affected area for up to 8 hours. Maximum: 4 patches/day. Do not use for >5 consecutive days. Treatment may be repeated ≥3 months as needed for return of pain (do not apply more frequently than every 3 months). Area should be pretreated with a topical anesthetic prior to patch application.

Dosage Forms, Patch: 8%

PRECAUTIONS: do not expose to eyes or mucous membranes; caution patient that pain may increase following initiation of treatment but will decrease thereafter; application site irritation/sensitivity

DRUG INTERACTIONS: No known significant interactions.

REFERENCES

Babbar S, Marier JF, Moukassi MS, et al, "Pharmacokinetic Analysis of Capsaicin After Topical Administration of High-Concentration Capsaicin Patch to Patients With Peripheral Neuropathic Pain," Ther Drug Monit, 2009, 31(4):502-10.

Backonja M, Wallace MS, Blonsky ER, et al, "NGX-4010, A High-Concentration Capsaicin Patch, for the Treatment of Postherpetic Neuralgia: A Randomised, Double-Blind Study," Lancet Neurol, 2008, 7(12):1106-12.

Bril V, England J, Franklin GM, et al, "Evidence-Based Guideline: Treatment of Painful Diabetic Neuropathy: Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation," Neurology, 2011, 76(20):1758-65.

Buchanan J and Zakrzewska J, "Burning Mouth Syndrome," Clin Evid (online March 14, 2008. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2907957/pdf/2008-1301.pdf>

Anand P, Bley K. Topical capsaicin for pain management: therapeutic potential and mechanisms of action of the new high-concentration capsaicin 8% patch. Br J Anaesth. 2011;107(4):490-502. doi:10.1093/bja/aer260

Bernstein JE, Korman NJ, Bickers DR, et al, "Topical Capsaicin Treatment of Chronic Postherpetic Neuralgia," J Am Acad Dermatol, 1989, 21(2 Pt 1):265-70.

Qutenza (capsaicin 8%) patch [prescribing information]. Morristown, NJ: Averitas Pharma Inc; October 2020

Willcockson HH, Chen Y, Han JE, et al, "Effect of Genetic Deletion of the Vanilloid Receptor TRPV1 on the Expression of Substance P in Sensory Neurons of Mice With Adjuvant-Induced Arthritis," Neuropeptides, 2010, 44(4):293-7

Price R, Smith D, Franklin G, et al. Oral and topical treatment of painful diabetic polyneuropathy: practice guideline update summary: report of the AAN guideline subcommittee. *Neurology*. 2022;98(1):31-43

Qutenza (capsaicin 8%) [prescribing information]. Morristown, NJ: Averitas Pharma Inc; March 2023.

Ellis CN, Berberian B, Sulica VI, et al. A double-blind evaluation of topical capsaicin in pruritic psoriasis. *J Am Acad Dermatol*. 1993;29(3):438-442. doi:10.1016/0190-9622(93)70208-b

The Capsaicin Study Group. Treatment of painful diabetic neuropathy with topical capsaicin. A multicenter, double-blind, vehicle-controlled study. The Capsaicin Study Group. *Arch Intern Med*. 1991;151(11):2225-2229.

Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/18/20

Date Reviewed/No Updates: 2/2/21 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/2/21

Date Reviewed/Updated: 8/3/21 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 8/3/21

Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/1/22

Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/31/23

Date Reviewed/No Updates: 2/13/24 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/13/24

Date Reviewed/Updated: 2/18/25 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/18/25

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Formatting changes; References Added
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added authorization criteria under muscle/joint pain: “burning mouth syndrome” References updated