

## About Qutenza<sup>®</sup> (capsaicin) 8% patch

Qutenza<sup>®</sup> (capsaicin) 8% patch is indicated for the management of neuropathic pain associated with post-shingles pain or postherpetic neuralgia (PHN). A single, 1-hour, *localized* treatment can provide 3 months of relief from pain associated with PHN.

The active ingredient in Qutenza<sup>®</sup> is synthetic prescription-strength capsaicin. Capsaicin is a naturally occurring compound found in chili peppers that gives them their heat sensation. Qutenza<sup>®</sup> harnesses the power of capsaicin in a *localized*, dermal delivery system that targets the nerves in the skin. It is applied directly to the skin at the painful site by a physician or healthcare professional under the close supervision of a physician. It is the first and only prescription-strength capsaicin product.

Qutenza<sup>®</sup> is non-narcotic and is unlikely to have drug-drug interactions. It can be used alone or in combination with other pain medications.

## How Qutenza<sup>®</sup> Works

Hyperactivity of specialized pain nerves in the skin is believed to contribute to nerve-related pain syndromes such as post-shingles nerve pain also known as PHN. The capsaicin in Qutenza<sup>®</sup> is believed to provide pain reduction by acting on these hyperactive pain nerves. The effect of capsaicin is reversed over time.

Qutenza<sup>®</sup> is applied by a physician or healthcare professional under the close supervision of a physician. A single, 1-hour, *localized* treatment can provide 3 months of relief from nerve pain associated with PHN. Up to 4 patches may be used and patches may be cut to conform to the size and shape of the painful area. Qutenza<sup>®</sup> is a *localized*, non-narcotic treatment and is unlikely to have drug-drug interactions. Treatment with Qutenza<sup>®</sup> may be repeated every 3 or more months as warranted by the return of pain, but not more frequently than every 3 months.

## Phase 3 Clinical Trial Results

The efficacy of Qutenza<sup>®</sup>, was established in two 12-week, double-blind, randomized, dose-controlled, multicenter studies. These studies enrolled patients with postherpetic neuralgia (PHN) and a baseline score of 3 to 9 on an 11-point Numerical Pain Rating Scale (NPRS) ranging from 0 (no pain) to 10 (worst possible pain). Qutenza<sup>®</sup> and a low dose control patch were each applied as a single 60-minute application.

1. A total of 402 patients with PHN were evaluated in one study; the Qutenza<sup>®</sup> group demonstrated a greater reduction in pain compared to the control group during the primary assessment at week 8. Some patients experienced a decrease in pain as early as week 1 that persisted throughout the 12-week study.
2. Efficacy, safety, and tolerability of Qutenza<sup>®</sup> were evaluated in a second study of 416 PHN patients. Following a single 1-hour application, the Qutenza<sup>®</sup> group demonstrated a greater reduction in pain compared to the control group during the primary assessment at week 8. Some patients experienced a decrease in pain as early as week 1 that persisted throughout the 12-week study.

## Indication

Qutenza<sup>®</sup> is indicated for the management of neuropathic pain associated with postherpetic neuralgia. Qutenza<sup>®</sup> was approved by the U.S. Food and Drug Administration on November 16, 2009.

## **About Postherpetic Neuralgia**

Postherpetic neuralgia is nerve pain that occurs after an attack of shingles. Shingles can damage nerves, and the pain from damaged nerves may feel like a sharp, burning, tingling, shooting, or numb sensation. The pain from PHN can persist long after the shingles rash clears up and can disrupt sleep, mood, work, and activities of daily living. The risk of developing PHN increases with age (especially in people over 60) and for patients who experienced severe pain or severe rash during the acute shingles episode.

## **IMPORTANT SAFETY INFORMATION**

Only physicians or healthcare professionals under the close supervision of a physician are to administer Qutenza<sup>®</sup> (capsaicin) 8% patch.

**Contraindications:** None.

### **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<sup>®</sup>, 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<sup>®</sup> treatment. In clinical trials, 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<sup>®</sup> treatment.

**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, and application-site papules.

## **About NeurogesX, Inc.**

NeurogesX, Inc. (Nasdaq: NGSX) is a San Francisco Bay Area–based biopharmaceutical company focused on developing and commercializing novel pain management therapies. NeurogesX was founded on the concept that use of prescription-strength capsaicin could help manage the pain associated with neuropathic pain conditions. Since its inception, NeurogesX has leveraged its passion to help people with pain to efficiently develop this concept and has made Qutenza<sup>®</sup> (capsaicin) 8% patch available to patients and physicians. In addition, we continue to apply our knowledge and expertise in the development of other novel treatments for pain.

The Company's lead product, Qutenza<sup>®</sup> (capsaicin) 8% patch, is a *localized* dermal delivery system containing prescription-strength capsaicin that is currently approved in the United States and the European Union. In Europe, Qutenza<sup>®</sup> will be marketed by Astellas Pharma Europe Ltd. (Astellas), the European subsidiary of Tokyo-based Astellas Pharma Inc.

Please visit the Qutenza<sup>®</sup> website at [www.Qutenza.com](http://www.Qutenza.com) to see complete Prescribing Information for Qutenza<sup>®</sup>.