



(capsaicin) 8% patch

# Patient's Guide

A single, 1-hour, localized treatment may provide 3 months of relief from post-shingles nerve pain

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

#### IMPORTANT SAFETY INFORMATION:

Treatment with Qutenza must be performed only by a healthcare provider. You should never apply or remove Qutenza yourself.

PLEASE SEE FULL PRESCRIBING INFORMATION.

# Learn how Qutenza® (capsaicin) 8% patch may help

# What medications are used to treat post-shingles nerve pain?

There are several medications approved by the Food and Drug Administration (FDA) for post-shingles nerve pain, also known as postherpetic neuralgia.

- ▶ Oral medicines, or pills, are taken daily and act on the nervous system.
- A skin patch is available that can be applied to the site of pain for up to 12 hours, once per day.



# Q

## What is Qutenza®?

Qutenza® is a patch that may provide 3 months of pain relief from a single, 1-hour application of the patch. Treatment may be repeated every 3 months or as warranted by the return of pain (not more frequently than every 3 months). The medicine in Qutenza® is prescription-strength capsaicin, which is the substance in chili peppers that gives them their heat sensation. Qutenza® is the first and only treatment of its kind to deliver prescription-strength capsaicin directly into the skin.

## **IMPORTANT SAFETY INFORMATION (continued):**

## **Warnings and Precautions:**

 Qutenza is not for use near eyes or mucous membranes. Do not sniff or inhale near the Qutenza patch as this may cause you to cough or sneeze.

# Learn how Qutenza® (capsaicin) 8% patch may help

# Q

## Is Qutenza® proven to work?

In clinical studies Qutenza® has been shown to relieve pain for up to 3 months in people with post-shingles nerve pain.¹ Qutenza® has been shown to be effective for patients who are already taking other pain medicines.² Qutenza® is unlikely to interact with other medicines you may be taking. Like any medicine, Qutenza® may not work for everyone. Only you and your doctor can decide if Qutenza® is right for you.



## **IMPORTANT SAFETY INFORMATION (continued):**

## Warnings and Precautions (continued):

- Do not touch the Qutenza patch with your hands. If you touch the patch, it may cause burning and stinging; if this occurs, tell your healthcare provider.
- Even though a numbing medicine is used on the skin before applying Qutenza, some patients may still experience substantial pain during the treatment. Tell your healthcare provider if you are experiencing pain; a cool compress or medicine for the pain can be provided to help lessen your discomfort.

# What you should know about Qutenza® (capsaicin) 8% patch

# What are the most common side effects of Qutenza®?

The most common side effects experienced by 5% or more of patients are: application site redness, application site pain, application site itching, small bumps where Qutenza® is applied, and nausea.<sup>1</sup>

# Why does Qutenza® have to be applied by my doctor or healthcare professional?

Qutenza® contains prescription-strength capsaicin capable of producing irritation of the eyes, skin, or other parts of the body. It must be applied by a doctor or healthcare professional who is familiar with proper Qutenza® administration, including handling it with special gloves and disposing it to prevent accidental contact.

Also, your blood pressure needs to be monitored during your treatment because pain during the treatment may cause your blood pressure to increase.

Please see Important Safety Information on page 11.

## **IMPORTANT SAFETY INFORMATION (continued):**

## Warnings and Precautions (continued):

- Qutenza can cause serious side effects including pain and increases in blood pressure during or right after treatment.
- Your healthcare provider should check your blood pressure during treatment with Qutenza.

# What you should know about Qutenza® (capsaicin) 8% patch

# Q

## What should I discuss with my doctor or healthcare professional before using Qutenza®?

Tell your doctor or healthcare professional if you:

- ▶ Have high or unstable blood pressure or if you have recently had any heart problems or stroke. If so, you may have an increased risk of heart problems or stroke during treatment, since treatment-related pain may cause an increase in your blood pressure. Your doctor or healthcare professional will monitor your blood pressure during and shortly after your Qutenza® treatment.
- Are taking any narcotic pain medicines such as codeine, hydrocodone, oxycodone, or morphine, among others. Your doctor needs this information in order to possibly select a different type of pain medicine to be used during your Qutenza® treatment if needed.
- Are pregnant or breastfeeding.



## **IMPORTANT SAFETY INFORMATION (continued):**

## Warnings and Precautions (continued):

- If you have high blood pressure that is not well controlled by medicine, or have had recent heart problems, stroke, or other vascular problems, you may be at increased risk and should discuss with your doctor whether Qutenza is right for you.
- If opioids are used to treat pain associated with the application procedure, these medicines may affect your ability to perform potentially hazardous activities such as driving or operating heavy machinery.

# Learn about the Qutenza® (capsaicin) 8% patch application

# Q

## What happens during the application?



## **Identify**

Your skin in the painful area should be dry and unbroken. Your doctor will mark the treatment area on your skin. If necessary, your hair in and around the treatment area may be clipped (not shaved) by your doctor or healthcare professional to ensure that the patch will stick. The treatment area will then be gently washed with mild soap and water and dried thoroughly.



#### Numb

A topical anesthetic will be applied to reduce discomfort associated with the application of Qutenza®. The topical anesthetic will be removed, and the treatment area will be gently washed with mild soap and water and dried thoroughly.

# Learn about the Qutenza® (capsaicin) 8% patch application

# Q

### What happens during the application?



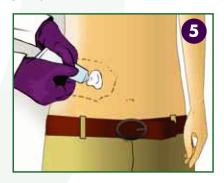
## **Apply**

The Qutenza® patch or patches (up to 4) can be cut to the shape of the painful area and applied to your skin for 60 minutes. During the treatment, you must not touch the patch or the treatment area. Your doctor or healthcare professional will carefully avoid exposing the capsaicin to your eyes, mucous membranes, face and scalp, and any skin outside the treatment area. In addition, care will be taken to prevent potential airborne capsaicin from being inhaled. It is common for the skin to become red or for you to feel a burning sensation during this time. Your doctor or healthcare professional may manage your pain with a cold pack or pain medicines.



Remove

After 60 minutes, the Qutenza® patch will be gently removed.



Cleanse

The final step is to cleanse your treatment area by applying a special Cleansing Gel that will be left on for at least 1 minute before it is removed. The treatment area will be gently washed with mild soap and water and dried thoroughly.

# During the Qutenza® (capsaicin) 8% patch treatment

# (a) Is there pain during the Qutenza® application?

Some pain during the treatment is common, due to the prescription-strength capsaicin in Qutenza®. It's important that you tell your doctor or healthcare professional how you are feeling during the application process. If you experience pain, tell your doctor or healthcare professional—they may help reduce your discomfort. Your healthcare professional may use cold packs or pain medicine to reduce treatment-related discomfort. Also, because the pain may cause an increase in blood pressure, your doctor or healthcare professional will measure your blood pressure during your treatment.

# What can I expect during my Qutenza® application?

For Qutenza® patients in clinical studies, temporary increases in pain were common on the day of treatment. Pain increases that occurred during patch application usually began to decrease after patch removal. On average, pain returned to pretreatment levels by the end of the treatment day and then remained at or below pretreatment levels. The adverse reactions of most Qutenza® patients were "mild" or "moderate."



# After the Qutenza® (capsaicin) 8% patch treatment

# What else should I remember about Qutenza®?

- Ask your doctor if someone should drive you home after the treatment.

  Qutenza® is unlikely to have an effect on your ability to drive, but some patients may require temporary use of pain-reducing medicines during or after their treatment. Some of these medicines (e.g., an opioid) may influence your ability to drive or use machinery on the days they are taken.
- Do not touch Qutenza® during treatment as this may burn or irritate your eyes, nose, face, scalp, or other sensitive areas.

The areas treated with Qutenza® may be sensitive to heat, so you may wish to avoid hot showers or baths, direct sunlight, and vigorous exercise for a few days following treatment.

# IMPORTANT SAFETY INFORMATION (continued): Side Effects:

In clinical studies, the most common drug-related side effects of Qutenza, which occurred in 5% or more of patients, included redness, pain, itching, or small bumps where Qutenza was applied, and nausea. You should tell your doctor if any side effects bother you or do not go away.

These are not all the side effects of Qutenza. For more information, ask your healthcare provider or pharmacist.

# Reimbursement support

Health insurance coverage of Qutenza® (capsaicin) 8% patch may vary from plan to plan. For more information about reimbursement support, contact:

# **Reimbursement Support**

**Call:** 877-900-6479, option 3

Monday-Friday 8AM-7PM EST

Click: www.Qutenza.com

# **BioPlus Specialty Pharmacy**

Call: 888-292-0744

# **Important Safety Information**

#### Indication:

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

#### **IMPORTANT SAFETY INFORMATION:**

Treatment with Qutenza must be performed only by a healthcare provider. You should never apply or remove Qutenza yourself.

#### **Contraindications:**

None

## **Warnings and Precautions:**

- Qutenza is not for use near eyes or mucous membranes. Do not sniff or inhale near the Qutenza patch as this may cause you to cough or sneeze.
- Do not touch the Qutenza patch with your hands. If you touch the patch, it may cause burning and stinging; if this occurs, tell your healthcare provider.
- Even though a numbing medicine is used on the skin before applying Qutenza, some patients may still experience substantial pain during the treatment. Tell your healthcare provider if you are experiencing pain; a cool compress or medicine for the pain can be provided to help lessen your discomfort.
- Qutenza can cause serious side effects including pain and increases in blood pressure during or right after treatment.
- Your healthcare provider should check your blood pressure during treatment with Qutenza.

- If you have high blood pressure that is not well controlled by medicine, or have had recent heart problems, stroke, or other vascular problems, you may be at increased risk and should discuss with your doctor whether Qutenza is right for you.
- If opioids are used to treat pain associated with the application procedure, these medicines may affect your ability to perform potentially hazardous activities such as driving or operating heavy machinery.

#### **Side Effects:**

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## **Adverse Event Reporting:**

Physicians, other health care 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.

For more information, ask your healthcare provider or pharmacist.

# Qutenza® (capsaicin) 8% patch for treating post-shingles nerve pain

## **Q**utenza®

- May provide 3 months of pain relief from a single, 1-hour application of the patch.
- Acts locally to treat your post-shingles nerve pain.
- Is not a narcotic and is unlikely to interact with other prescription drugs.

### **IMPORTANT SAFETY INFORMATION:**

### **Side Effects:**

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PLEASE SEE FULL PRESCRIBING INFORMATION.





