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Capsaicin 8% Patch (Qutenza)

??? ??????: 30 ??????/?????? 2017

The following serious adverse reactions are discussed elsewhere in the labeling:

]**WARNINGS AND PRECAUTIONS** Application-Associated Pain [see

]**WARNINGS AND PRECAUTIONS** Increase in Blood Pressure [see

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in clinical practice.

Across all controlled and uncontrolled trials, more than 1,600 patients have received Qutenza (capsaicin 8% patch) . A total of 394 patients received more than one treatment application and 274 patients were followed for 48 weeks or longer.

In controlled clinical studies, 98% of patients completed ? 90% of the intended patch application duration. Among patients treated with Qutenza (capsaicin 8% patch) , 1% discontinued prematurely due to an adverse event.

Controlled Clinical Studies

Common Adverse Reactions

Adverse events occurring in ? 5% of patients in the Qutenza (capsaicin 8% patch) group and at an incidence greater than in the control group were application site erythema, application site pain, application site pruritus and application site papules.

Table 1 summarizes all adverse reactions, regardless of causality, occurring in ? 1% of patients with postherpetic neuralgia in the Qutenza (capsaicin 8% patch) group for which the incidence was greater than in the control group. The majority of application site reactions were transient and self-limited. Transient increases in pain were commonly observed on the day of treatment in patients treated with Qutenza (capsaicin 8% patch) . Pain increases occurring during patch application usually began to resolve after patch removal. On average, pain scores returned to baseline by the end of the treatment day and then remained at or below baseline levels. A majority of Qutenza (capsaicin 8% patch) -treated patients in clinical studies had adverse reactions with a maximum intensity of "mild" or "moderate".

TABLE 1: Treatment-emergent adverse reaction incidence (%) in controlled trials in Postherpetic Neuralgia (Events in ? 1% of Qutenza (capsaicin 8% patch) -treated patients and at least 1% greater in the Qutenza (capsaicin 8% patch) group than in the Control group)

Control 60 minutes (N = 495) %	Qutenza (capsaicin 8% patch) 60 minutes (N = 622) %	Body System Preferred Term
		General Disorders and Administration Site Conditions
54	63	Application Site Erythema
21	42	Application Site Pain
4	6	Application Site Pruritus
3	6	Application Site Papules
1	4	Application Site Edema
1	2	Application Site Swelling
1	2	Application Site Dryness
		Infections and Infestations
2	4	Nasopharyngitis
1	2	Bronchitis
1	3	Sinusitis
		Gastrointestinal Disorders

2	5	Nausea
1	3	Vomiting
		Skin and Subcutaneous Tissue Disorder
< 1	2	Pruritus
		Vascular Disorders
1	2	Hypertension

Other Adverse Reactions Observed During the Clinical Studies of Qutenza (capsaicin 8% patch)

Application site urticaria, Application site paresthesia, Application site dermatitis, Application site **:*General Disorders and Administration Site Conditions*** hyperesthesia, Application site excoriation, Application site warmth, Application site anesthesia, Application site bruising, Application site inflammation, Application site exfoliation, Peripheral edema

Headache, Burning sensation, Peripheral sensory neuropathy, Dizziness, Dysgeusia, Hyperesthesia, Hypoesthesia **:*Nervous System Disorders***

Cough, Throat irritation **:*Respiratory, Thoracic and Mediastinal Disorders***

Abnormal skin odor **:*Skin and Subcutaneous Tissue Disorders***