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EPAR summary for the public

Qutenza

capsaicin

This is a summary of the European public assessment report (EPAR) for Qutenza. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Qutenza.

What is Qutenza?

Qutenza is a cutaneous patch (a patch that delivers a medicine into the skin). It contains the active substance capsaicin (8%).

What is Qutenza used for?

Qutenza is used to treat peripheral neuropathic pain (pain that is caused by damage to the nerves) in adults. It can be used alone or together with other medicines for pain.

The medicine can only be obtained with a prescription.

How is Qutenza used?

Qutenza should be applied by a doctor or by a healthcare professional under the supervision of a doctor. It is applied to the most painful areas of the skin. The painful area should be determined by a doctor and marked on the skin. Qutenza can only be applied to unbroken, non-irritated, dry skin.

Patches can be cut to match the area to cover. No more than four patches should be used on the patient at the same time. Before applying Qutenza, the area may be treated with a local anaesthetic to numb it; this helps to reduce discomfort. Alternatively, medicines for pain may be taken. Qutenza should remain in place for 30 minutes for the feet and 60 minutes for other parts of the body. Once the patch is removed, the area is cleaned using the cleansing gel provided. It may take up to three weeks



for Qutenza to have an effect. The treatment may be repeated every three months depending on the patient's symptoms.

Qutenza can cause a burning sensation on the skin. Because of this, healthcare professionals should wear nitrile gloves while applying and removing the patch.

How does Qutenza work?

The active substance in Qutenza, capsaicin, is a substance normally found in chilli peppers. It stimulates the 'transient receptor potential vanilloid 1' (TRPV1) receptor which is found in the nerves in the skin that detect pain. The rapid release of high doses of capsaicin from Qutenza overstimulates the TRPV1 receptors so they become less sensitive to the stimuli that normally cause neuropathic pain.

How has Qutenza been studied?

Qutenza has been compared with control patches containing lower amounts of capsaicin (0.04%) in four main studies involving a total of 1,619 adults with moderate to severe neuropathic pain. All of the patients had neuropathic pain due to either post-herpetic neuralgia (pain that occurs in people who have had shingles, an infection caused by the varicella zoster virus) or HIV-associated neuropathy (damage to the nerves caused by HIV infection). A fifth study compared Qutenza with a placebo (dummy) patch in 369 patients with painful peripheral diabetic neuropathy, a form of neuropathic pain associated with diabetes; a supportive study looked at repeated treatment over one year. The main measure of effectiveness in all main studies was the reduction in the 24-hour pain score during an eight- or 12-week period after application of the patch.

What benefit has Qutenza shown during the studies?

Qutenza was more effective at reducing neuropathic pain than the control patches. In the two studies of patients with post-herpetic neuralgia, the reduction in pain scores after eight weeks was 30 and 32% in patients who were given Qutenza, compared with 20 and 24% in patients who received the control patches. In one of the studies of patients with HIV-associated neuropathy, patients who were given Qutenza experienced a 23% reduction in pain scores after 12 weeks compared with an 11% reduction in patients who were given the control. In the second study of patients with HIV-associated neuropathy, although Qutenza reduced pain by 30% it was not shown to be more effective than the control. In patients with painful peripheral diabetic neuropathy, the reduction in pain score from week 2 to after 8 weeks with Qutenza was about 27% compared with 21% for the placebo. Supportive data showed benefit when Qutenza was repeated over a 1-year period in combination with other treatments.

What is the risk associated with Qutenza?

The most common side effects with Qutenza (seen in more than 1 patient in 10) are pain and redness at the site of application. For the full list of all side effects and restrictions with Qutenza, see the package leaflet.

Why has Qutenza been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Qutenza's benefits are greater than its risks and recommended that Qutenza be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Qutenza?

A risk management plan has been developed to ensure that Qutenza is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Qutenza, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that makes Qutenza will make sure that an educational programme is available for healthcare professionals who will prescribe Qutenza. The programme will include information on how to administer, handle and dispose of Qutenza and on warnings and precautions that should be considered during treatment.

Other information about Qutenza

The European Commission granted a marketing authorisation valid throughout the European Union for Qutenza on 15 May 2009.

The full EPAR for Qutenza can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Qutenza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2015.