


EDUCATIONAL MATERIAL

Prescribers' Administration Guide for Qutenza[®] 179 mg Cutaneous Patch (capsaicin)

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Risk minimisation material concerning Qutenza capsaicin 179 mg cutaneous patch for healthcare professionals

Prescribers should familiarise themselves with this administration guide before handling Qutenza. For further information about Qutenza, please refer to the Summary of Product Characteristics (SPC).

DO NOT prescribe Qutenza if your patient has hypersensitivity to the active substance (capsaicin) or to any of the excipients (see section 6.1 of the SPC).

Qutenza must be used only on dry, intact (unbroken) skin and not on the face, above the hairline of the scalp, and/or in proximity to mucous membranes.

Unintended exposure

- Unintended exposure to capsaicin may cause irritation of eyes, mucous membranes, respiratory tract and skin in patients and healthcare professionals. Healthcare professionals should ensure that the recommended protective measures as outlines in SPC Section 4.2 are applied appropriately.
- If capsaicin comes in contact with skin not intended to be treated, cleansing gel should be applied for 1 minute and wiped off with dry gauze to remove any remaining capsaicin from the skin surface. After the cleansing gel has been wiped off, the area should be gently washed with soap water.
- If capsaicin comes in contact with eyes or mucous membranes, these should be flushed or rinsed with cold water.

Rare cases of worsening/non-resolving respiratory irritation due to accidental exposure to Qutenza have been reported, mainly in health care professionals applying the product. If respiratory irritation worsens or does not resolve, the affected individual should be carefully considered for whether or not there is need for re-exposure to Qutenza based on the assessment of a risk-benefit profile.

Please consider the following before using Qutenza:

Does your patient have hypertension or cardiovascular disease?

- For patients with unstable or poorly controlled hypertension or a history of cardiovascular disease, the risk of adverse cardiovascular events due to the potential stress of the procedure should be considered prior to initiating Qutenza therapy.
- Monitor your patient's blood pressure prior to and during Qutenza therapy. Particular attention should be given to diabetic patients with or without comorbidities of coronary artery disease, hypertension and cardiovascular autonomic neuropathy.

Does your patient have diabetes mellitus?

- Diabetic patients with distal sensory neuropathy and/or vascular insufficiency may be at particular risk of skin lesions at the treatment site.
- In patients with painful diabetic peripheral neuropathy, a careful visual examination of the feet should be undertaken prior to treatment with Qutenza and at subsequent clinic visit, to detect skin lesions related to underlying neuropathy and vascular insufficiency.

Does your patient have intact skin in the treatment area?

- Examine your patient's skin prior to each Qutenza patch application for signs of broken skin or ulceration.

Does your patient have pre-existing or developed during treatment decreased sensory function?

- Use Qutenza with caution in patients with pre-existing changes in sensory function and clinically assess your patient for signs of worsening sensory loss before continuing Qutenza treatment.

Do you or your patient have worsening/non-resolving respiratory irritation?

- In case such symptoms would occur, the concerned individual should carefully consider for whether or not there is need for re-exposure to Qutenza.

PRACTICAL PRECAUTIONS for the healthcare professional:

- Administer Qutenza treatment in a well-ventilated area.
- Wear nitrile gloves (not latex) at all times while handling Qutenza. In addition, the use of a mask and protective glasses is recommended.
- Avoid direct contact with Qutenza patch, used gauze or used cleansing gel, and avoid touching eyes, mouth or other sensitive areas during treatment.
- Do not hold Qutenza patches near eyes or mucous membranes.
- Do not apply Qutenza to broken skin.
- Do not apply Qutenza to the following areas: the face, above the scalp hairline or in proximity to eyes and mucous membranes.
- Dispose of all Qutenza patches and associated materials appropriately in a sealed polyethylene medical waste bag.
- The cleansing gel for Qutenza contains butylhydroxyanisole, which may cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.



1. The treatment setting:

- A well-ventilated treatment room with water available.
- Provide a means of distraction for the patient to occupy them during the application procedure, such as reading materials.



2. Briefing the patient:

- **Before** beginning the treatment, explain the application procedure to the patient.
- Inform the patient that **treatment site reactions such as pain or burning sensation, erythema, pruritus and swelling** may occur, and advise them to inform the attending staff should any side reactions occur.
- If the patient is left alone during the application procedure, inform them on how to use the means of contacting someone quickly.

Please also inform your patients prior to Qutenza therapy about:

- the risk of reductions in sensory function which are generally minor and temporary after Qutenza treatment i.e. the ability to detect heat and sharp pain stimuli.
- in rare occasions serious skin injuries such as burns may occur following Qutenza therapy.

3. Identify:

- The treatment area should be determined by identifying areas of dynamic and pinprick allodynia and any painful regions that extend beyond the area of allodynia.
- Once identified, mark the painful area on the skin using a skin marker that will not rub off during the procedure.
- Trace the treatment area onto a stencil/transparency or directly onto the Qutenza patch. Use anatomical markings to ensure the patch is applied in the correct position.



4. Prepare the Patient:

- If removal of hair from the treatment area is necessary, it must be clipped rather than shaved.
- The treatment area may be pre-treated with a topical anaesthetic or the patient may be administered an oral analgesic prior to application of Qutenza to reduce potential treatment-associated discomfort.
- If used, topical anaesthetic should be removed prior to applying Qutenza.
- Before applying the Qutenza patch, the skin should always be gently washed and dried thoroughly.

5. Apply:

- Wear nitrile gloves at all times while handling Qutenza and cleaning treatment areas. Do not wear latex gloves as they do not provide adequate protection.
- The use of a mask and protective glasses is recommended to prevent eye and respiratory tract irritation, particularly during patch application and removal.
- Qutenza is a single-use transparent patch that can be cut to match the size and shape of the treatment area.
- Cut Qutenza to match the size and shape of the treatment area before the release liner is removed. Do not remove the release liner until just before application.
- There is a diagonal cut in the release liner to aid in its removal. Peel and fold a section of the release liner, then place the adhesive side of the Qutenza patch onto the treatment area.
- Hold the patch in place then slowly and carefully peel away the release liner while simultaneously smoothing the patch onto the skin with the other hand.
- Allow the patch to remain in place for 30 minutes for the feet or 60 minutes for any other area.



- If capsaicin comes in contact with eyes or mucous membranes, these should be flushed or rinsed with cold water. If irritation of airways, eyes, or mucous membranes occurs, the affected individual should leave the Qutenza treatment area. Provide appropriate medical care if shortness of breath develops.
- In patients reporting severe treatment-associated pain, the Qutenza patch should be removed and the skin examined for chemical burn.

Tips to aid patch adhesion

- For Qutenza to be effective, it is critical to ensure that there is complete contact between the patch and the skin, with no air bubbles and no moisture.
- Apply pressure to the patch during application, by using gauze or bandages to wrap the treatment area, having the patient wear tight socks, using weights or sandbags or asking the patient to lie on the treatment area can all aid adhesion.
- Other techniques to improve adhesion include cutting the patch into smaller pieces or making cuts into the patch; pulling the skin taut before application; and warming the skin if necessary particularly on cold feet.



6. Managing treatment-associated discomfort:

- Local cooling provides an effective way of managing any treatment-related discomfort and may be used along with oral analgesics, if necessary, to treat acute pain during and following the procedure.
- The use of wet compresses during the Qutenza application should be avoided as moisture can impact patch adhesion.
- Use chilled (not frozen) cool packs on the treated area after the Qutenza application. Wrap the cool packs in material to avoid direct contact with the skin.
- Provide patients with cool packs to manage the pain at home.
- Advise patients, when appropriate, that they can also use over-the-counter pain killers when cooling does not provide adequate pain relief.

7. Remove

- Wear nitrile gloves, face mask and protective glasses prior to patch removal.
- Slowly and gently remove the Qutenza patch by rolling it inward to minimise the risk of aerosolisation of capsaicin.
- Dispose of all materials in a sealed polyethylene medical waste bag.



8. Cleanse

- Apply cleansing gel liberally to the treatment area and leave on for at least 1 minute.
- Wipe off the cleansing gel with dry gauze moving from the outer border of the treatment area to the midpoint and then gently wash the affected area with soap and water.
- Do not let the capsaicin-contaminated water contact the surrounding skin.



9. Advise:

- Capsaicin can continue to leach out of the skin following cleansing; therefore advise the patient not to touch the treated area for 1-2 days. Patients receiving treatment of the hands could be advised to wear gloves for 1–2 days following treatment.
- Inform the patient that the treated area may be sensitive (to heat, hot showers/baths, direct sunlight, vigorous exercise, etc.) for a few days.
- Inform the patient that burning sensation may increase at night and that they may use cooling measures or oral analgesics to manage any discomfort, as described under section 6.
- If possible, provide patients with the information sheet included in this document, for reference at home.

10. Patient follow-up:

- All patients should be followed up on a regular basis.
- Patients should be provided with a number to call if they need any assistance.

REPORTING OF ADVERSE EVENTS

Adverse events can also be reported to:

- **Local Qualified Person Responsible For Pharmacovigilance**
E-mail: grunenthal.sa@biomapas.com
- **STADA KSA Scientific Office**
E-mail: pv.ksa@stada.com
- **The National Pharmacovigilance Centre (NPC)
Saudi Food and Drug Authority**
Call Center: 19999
E-mail: mailto:npc.drug@sfda.gov.sa
Fax: +966-11-205-7662
Website: <https://ade.sfda.gov.sa/>





Patient Information Leaflet

This information sheet can be provided to the patient for future reference.

- **IMPORTANT SAFETY INFORMATION: Treatment with QUTENZA must be performed only by a healthcare provider. You should never apply or remove QUTENZA yourself.**
- **Store flat in original sachet and carton. Store below 30°C. Keep this medicine out of sight and reach of children.**
- Do not touch Qutenza patch or other materials that have come in contact with the treated areas as it may cause burning and stinging. Do not touch or scratch the treatment area, and do not let anyone else touch the treatment area. Do not touch your eyes, mouth or other sensitive areas as it may cause irritation on and pain. If this happens, flush or rinse with cold water.
- You may notice that you have less feeling for hot or sharp pain at the site where Qutenza was applied. This is usually temporary and the feeling will return to normal in a few days after your treatment.
- Local side effects at the treatment area, such as redness, itchiness, burning pain or swelling are common and usually disappear in few days.
- The burning sensation may increase again at night if the treatment area becomes hot.
- Use localised cooling or over-the-counter pain killers to manage any discomfort.
- For a few days after treatment, avoid hot baths or showers, or vigorous exercise.
- Do not apply local heat on the treatment area (e.g. heating pads or hot water in bags or bottles).
- Rare cases of serious burns have been reported to occur on the skin where Qutenza has been applied. If you experience worsening pain, swelling, peeling or blistering of skin, seek medical attention immediately.

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.