

IMPORTANT RISK MINIMISATION INFORMATION  
FOR HEALTHCARE PROFESSIONALS

**Prescribers' Administration  
Guide for Qutenza (capsaicin)**

Version 5.2 January 2025

## **Risk minimisation material concerning the capsaicin 179mg cutaneous patch for healthcare professionals**

### **SUMMARY OF WARNINGS AND PRECAUTIONS FOR USE**

Prescribers should familiarise themselves with this administration guide before handling the patch. For further information about this medicine, please refer to the Summary of Product Characteristics (SmPC) available on [www.medicines.ie](http://www.medicines.ie) and [www.hpra.ie](http://www.hpra.ie).

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

The patch 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.

### **WARNINGS AND PRECAUTIONS**

#### **PLEASE CONSIDER THE FOLLOWING BEFORE USING THE PATCH:**

##### **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 outlined in SmPC Section 4.2 are applied appropriately.
- If capsaicin comes in contact with skin not intended to be treated, cleansing gel should be applied for one 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.
- If irritation of airways, eyes or mucous membranes occurs, the affected individual should leave the treatment area. Appropriate medical care should be provided if shortness of breath develops. If respiratory irritation (see also SmPC Section 4.8) worsens or does not resolve, the affected individual should carefully consider being re-exposed to the patch.

### **Increase in blood pressure**

- As a result of treatment-related increases in pain, transient increases in blood pressure (on average <8.0mm Hg) may occur during and shortly after the treatment. Monitor your patient's blood pressure prior to and during the treatment. Particular attention should be given to diabetic patients with or without comorbidities of coronary artery disease, hypertension and cardiovascular autonomic neuropathy.
- 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 capsaicin patch therapy.

### **Dermal assessment**

- In patients with painful diabetic peripheral neuropathy, a careful visual examination of the feet should be undertaken prior to each application of the patch and at subsequent clinic visits to detect skin lesions related to underlying neuropathy and vascular insufficiency.

### **Treatment related discomfort**

- Patients experiencing pain during and after patch application should be provided with supportive treatment such as local cooling or oral analgesics.

### **Sensory function**

- Be aware and inform your patient about the risk of reductions in sensory function which are generally minor and temporary after treatment i.e. the ability to detect heat and sharp pain stimuli.
- Use the patch with caution in patients with reduced sensation in the feet and in those at risk for such changes in sensory function.
- Clinically assess all patients with pre-existing sensory deficits for signs of sensory loss prior to each application of the patch. If sensory loss is detected or worsens, capsaicin patch treatment should be reconsidered.

## **Monitoring and management of local reactions**

- The cleansing gel for the capsaicin patch contains butylhydroxyanisole, which may cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.
- Inform your patient prior to capsaicin patch therapy about the increased risk of temporary local skin reactions i.e. burning pain, erythema, pruritus and swelling.
- Application site reactions, such as transient local applications site burning, pain, erythema and pruritus are common or very common. In addition, there have been reported cases of burns, including second and third degree burns, in patients treated with capsaicin patches (see SmPC section 4.8).
- In patients reporting severe treatment associated pain, the patch should be removed and the skin examined for chemical burn.

## **Non-resolving respiratory irritation**

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

- Rare cases of worsening/non-resolving respiratory irritation due to accidental exposure to capsaicin have been reported, mainly in healthcare professionals applying the product. In case such symptoms would occur, the concerned individual should carefully consider re- exposure to the patch.

## **PRACTICAL PRECAUTIONS:**

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

## 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 site 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 capsaicin patch therapy about:

- the risk of reductions in sensory function which are generally minor and temporary after treatment i.e. the ability to detect heat and sharp pain stimuli.
- rare occasions in which serious skin injuries such as burns may occur following capsaicin patch 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 patch. Use anatomical markings to ensure the patch is applied in the correct position.



### 4. Prepare:

- 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 patch application to reduce potential treatment-associated discomfort.
- The topical anaesthetic should be applied to cover the entire treatment area and surrounding 1 to 2 cm.
- If used, topical anaesthetic should be removed prior to applying the patch.
- Before applying the patch, the skin should always be gently washed and dried thoroughly.

## 5. Apply:

- Wear nitrile gloves at all times while handling the patch 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.
- This medicine is a single-use transparent patch and can be cut to match the size and shape of the treatment area.
- Cut the patch 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 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 treatment area. Provide appropriate medical care if shortness of breath develops.
- In patients reporting severe treatment-associated pain, the patch should be removed and the skin examined for chemical burn.

## Tips to aid patch adhesion

For the patch 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:

- Provide 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 application should be avoided as moisture can impact patch adhesion.
- Use chilled (not frozen) cool packs on the treated area after the 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.
- Patients may also be provided with supportive treatment such as oral analgesics where appropriate.

## 7. Remove:

- Wear nitrile gloves, face mask and protective glasses prior to patch removal.
- Slowly and gently remove the 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 following treatment. Patients receiving treatment to 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 the 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, to take home with them, detailing the advice given, as a reminder.

## 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.

Healthcare professionals are asked to report any  
suspected adverse reactions via HPRA  
Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie)

Adverse events should also be reported to:  
[drugsafety.IE@grunenthal.com](mailto:drugsafety.IE@grunenthal.com)

FURTHER INFORMATION AVAILABLE FROM:

Grünenthal Pharma Ltd, 4045 Kingswood Road, Citywest Business Park, Citywest, Co. Dublin, Ireland.

To request a hard copy of this guide, please email: [IEmedicalinformation@grunenthal.com](mailto:IEmedicalinformation@grunenthal.com)

FOR FULL PRESCRIBING INFORMATION REFER TO THE SUMMARY OF PRODUCT CHARACTERISTICS.

As prescribing information may vary from country to country, see local prescribing information for full details.

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This educational material fulfils the conditions of the marketing authorisation. Approved by the HPRA on 20.Jan.2025