

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Qutenza 179 mg cutaneous patch

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 280 cm² cutaneous patch contains a total of 179 mg of capsaicin or 640 micrograms of capsaicin per cm² of patch (8 % w/w).

Excipient with known effect: Each 50 g tube of cleansing gel for Qutenza contains 0.2 mg/g butylhydroxyanisole (E320).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous patch.

Each patch is 14 cm x 20 cm (280 cm²) and consists of an adhesive side containing the active substance and an outer surface backing layer. The adhesive side is covered with a removable, clear, unprinted, diagonally cut, release liner. The outer surface of the backing layer is imprinted with 'capsaicin 8%'.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Qutenza is indicated for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.

4.2 Posology and method of administration

Posology

Qutenza should be applied to the most painful skin areas (using up to a maximum of 4 patches). The painful area should be determined by the physician and marked on the skin. Qutenza must be applied to intact, non-irritated, dry skin, and allowed to remain in place for 30 minutes for the feet (e.g. HIV-associated neuropathy) and 60 minutes for other locations (e.g. postherpetic neuralgia). Qutenza treatments may be repeated every 90 days, as warranted by the persistence or return of pain.

The Qutenza cutaneous patch should be applied by a physician or by a health care professional under the supervision of a physician. Direct contact with Qutenza, used gauze or used cleansing gel should be avoided: See below Method of administration - Precaution to be taken before manipulating or administering the product.

Patches should not be held near eyes or mucous membranes.

If necessary, hairs in the affected area should be clipped to promote patch adherence (do not shave). The treatment area(s) should be gently washed with soap and water. Following hair removal and washing, the skin should be thoroughly dried.

The treatment area may be pre-treated with a topical anaesthetic or the patient might be administered an oral analgesic prior to application of Qutenza to reduce potential application related discomfort. The topical anaesthetic should be applied to cover the entire Qutenza treatment area and surrounding 1 to 2 cm. The topical anaesthetic or oral analgesic should be used in accordance with the product's instructions for use. In clinical trials, patients were pre-treated with topical lidocaine (4%), lidocaine (2.5%)/prilocaine (2.5%) or with 50 mg of tramadol. The anaesthetic cream should be removed prior to applying Qutenza and the skin washed and dried thoroughly.

Paediatric population

The safety and efficacy of Qutenza in children from birth to 18 years has not been established. No data are available.

Patients with renal and/or hepatic impairment

No dose adjustment is required for patients with renal or hepatic impairment.

Method of administration

Precautions to be taken before manipulating or administering the product

Nitrile gloves should be worn at all times while handling Qutenza and cleaning treatment areas. Latex gloves should NOT be worn as they do not provide adequate protection. Use of mask and protective glasses should also be considered, particularly during the removal of the patch.

These precautions should be taken to avoid unintentional contact with the patches or other materials that have come in contact with the treated areas. This may result in transient erythema and burning sensation (with mucous membranes being particularly susceptible), eye pain, eye and throat irritation and cough.

Instructions for use

Qutenza is a single use patch and can be cut to match the size and shape of the treatment area. Qutenza should be cut prior to removal of the release liner. The release liner should NOT be removed until just prior to application. There is a diagonal cut in the release liner to aid in its removal. A section of the release liner should be peeled and folded and the adhesive side of the printed patch placed on the treatment area. The patch should be held in place. The release liner should slowly and carefully be peeled from underneath with one hand while the patch should simultaneously be smoothed onto the skin with the other to ensure that there is complete contact between the patch and the skin, with no air bubbles and no moisture.

When treating feet, Qutenza patches can be wrapped around the dorsal, lateral and plantar surfaces of each foot to completely cover the treatment area.

To ensure Qutenza maintains contact to the treatment area, stretchable socks or rolled gauze may be used.

The Qutenza patches should be removed gently and slowly by rolling them inward to minimize the risk of aerosolisation of capsaicin. After removal of Qutenza, cleansing gel should be applied liberally to the treatment area and left on for at least one minute. Cleansing gel should be wiped off with dry gauze to remove any remaining capsaicin from the skin. After the cleansing gel has been wiped off, the area should be gently washed with soap and water.

Acute pain during and following the procedure should be treated with local cooling (such as a cool compress) and oral analgesics (e.g., short-acting opioids).

Used patches should be disposed of immediately after use in an appropriate medical waste container.

For instructions on handling and disposal of the treatment materials see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Health care professionals should wear nitrile gloves when handling patches and cleansing treatment areas. See section 4.2, Method of administration - Precaution to be taken before manipulating or administering the product.

Qutenza should 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.

Monitoring and management of application site reactions

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 degree burns, in patients treated with capsaicin patches. See section 4.8. In patients reporting severe pain, the patch should be removed and the skin examined for chemical burn.

If Qutenza 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 and water. If burning of eyes, skin, or airway occurs, the affected individual should be removed from the vicinity of Qutenza. Eyes or mucous membranes should be flushed or rinsed with water. Appropriate medical care should be provided if shortness of breath develops.

As a result of treatment-related increases in pain, transient increases in blood pressure (on average < 8.0 mm Hg) may occur during and shortly after the Qutenza treatment. Blood pressure should be monitored during the treatment procedure. Patients experiencing increased pain should be provided with supportive treatment such as local cooling or oral analgesics (i.e., short acting opioids). For patients with unstable or poorly controlled hypertension or a recent history of cardiovascular events, the risk of adverse cardiovascular reactions due to the potential stress of the procedure should be considered prior to initiating Qutenza treatment.

Patients using high doses of opioids may not respond to oral opioid analgesics when used for acute pain during and following the treatment procedure. A thorough history should be reviewed prior to initiating treatment and an alternative pain reduction strategy in place prior to Qutenza treatment in patients with suspected high opioid tolerance.

Though no treatment-related reductions in neurological function have been observed in clinical trials with Qutenza, minor and temporary changes in sensory function (e.g., heat detection) have been reported following administration of capsaicin. Patients with increased risk for adverse reactions due to minor changes in sensory function should be cautious when using Qutenza.

Diabetic Neuropathy

There is only limited experience with Qutenza in patients with Painful Diabetic Neuropathy (PDN). Repeated treatments with Qutenza in patients with PDN have not been studied.

Cleansing gel

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.

4.5 Interaction with other medicinal products and other forms of interaction

No formal interaction studies with other medicinal products have been performed as only transient low levels of systemic absorption have been shown to occur with Qutenza.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of capsaicin in pregnant women. Based on human pharmacokinetics, which show transient, low systemic exposure to capsaicin, the likelihood that Qutenza increases the risk of developmental abnormalities when given to pregnant women is very low. However, caution should be exercised when prescribing to pregnant women.

Breast-feeding

It is unknown whether capsaicin/metabolites are excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of capsaicin/metabolites in milk (for details see 5.3).

A risk to the newborns/infants cannot be excluded.

Breast-feeding should be discontinued during treatment with Qutenza.

Fertility

There is no data available on fertility.

4.7 Effects on ability to drive and use machines

Qutenza has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

Of the 1,327 patients treated with Qutenza in randomized controlled trials, 883 (67%) reported adverse reactions considered related to the medicinal product by the investigator. The most commonly reported adverse reactions were transient local applications site burning, pain, erythema and pruritus. Adverse reactions were transient, self-limited and usually mild to moderate in intensity. In all controlled trials, the discontinuation rate due to adverse reactions was 0.8% for patients receiving Qutenza and 0.6% for patients receiving control.

Tabulated list of adverse reactions

In Table 1 below all adverse reactions, which occurred at an incidence greater than control and in more than one patient in controlled clinical trials in patients with PHN and painful HIV-AN, are listed by system organ class and frequency: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$) and not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 1: Treatment-emergent related adverse reaction incidence in controlled trials

System organ class and frequency	Adverse reaction
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Infections and infestations	
Uncommon	Herpes zoster
Nervous system disorders	
Uncommon	Dysgeusia, hypoesthesia, burning sensation
Eye disorders	
Uncommon	Eye irritation
Cardiac disorders	
Uncommon	First degree atrio-ventricular (AV) block, tachycardia, palpitations
Vascular disorders	
Uncommon	Hypertension
Respiratory, thoracic and mediastinal disorders	
Uncommon	Cough, throat irritation
Gastrointestinal disorders	
Uncommon	Nausea
Skin and subcutaneous tissue disorders	
Uncommon	Pruritus
Musculoskeletal and connective tissue disorders	
Uncommon	Pain in extremity, muscle spasms
General disorders and administration site conditions	
Very common	Application site pain, application site erythema
Common	Application site pruritus, application site papules, application site vesicles, application site oedema, application site swelling, application site dryness
Uncommon	Application site urticaria, application site paraesthesia, application site dermatitis, application site hyperaesthesia, application site inflammation, application site reaction, application site irritation, application site bruising, peripheral oedema
Investigations	
Uncommon	Increased blood pressure
Injury, poisoning and procedural complications	
Not known	Burns second degree, accidental exposure (including eye pain, eye and throat irritation and cough)

No treatment-related reductions in neurological function, as evaluated by Quantitative Sensory Testing (QST) and neurological examinations, have been observed during clinical trials in patients with peripheral neuropathic pain. Temporary, minor changes in heat detection (1°C to 2°C) and sharp sensations were detected at the Qutenza application site in clinical trials with healthy volunteers .

4.9 Overdose

No case of overdose has been reported. Qutenza is required to be administered by a physician or under the supervision of a physician. Therefore, overdosing is unlikely to occur. Overdose may be associated with severe application site reactions, e.g. application site pain, application site erythema, application site pruritus. In case of suspected overdose, the patches should be removed gently, cleansing gel should be applied for one minute and then wiped off with dry gauze and the area should be gently washed with soap and water. Supportive measures should be taken as clinically needed. There is no antidote to capsaicin.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics, Other local anaesthetics, ATC code: N01BX04

Mechanism of action

Capsaicin, or 6-nonenamide, N-[(4-hydroxy-3-methoxyphenyl) methyl]-8-methyl, (6E), is a highly selective agonist for the transient receptor potential vanilloid 1 receptor (TRPV1). The initial effect of capsaicin is the activation of TRPV1-expressing cutaneous nociceptors, which results in pungency and erythema due to the release of vasoactive neuropeptides.

Pharmacodynamic effects

Following capsaicin exposure, cutaneous nociceptors become less sensitive to a variety of stimuli. These later-stage effects of capsaicin are frequently referred to as “desensitization” and are thought to underlie the pain relief. Sensations from non TRPV1-expressing cutaneous nerves are expected to remain unaltered, including the ability to detect mechanical and vibratory stimuli. Capsaicin-induced alterations in cutaneous nociceptors are reversible and it has been reported and observed that normal function (the detection of noxious sensations) returns within weeks in healthy volunteers.

Clinical Efficacy

Efficacy of a single 30-minute application of Qutenza to the feet has been shown in controlled clinical trials conducted in patients with painful HIV-AN. Efficacy of a single 60-minute application of Qutenza to locations other than the feet has been shown in controlled clinical trials conducted in patients with PHN. Pain reduction was observed as early as week 1 and was maintained throughout the 12-week study period. Qutenza has been shown to be effective when used alone or when used in combination with systemic medicinal products for neuropathic pain.

5.2 Pharmacokinetic properties

The capsaicin contained in Qutenza is intended for delivery into the skin. *In vitro* data (active substance dissolution and skin permeation assays) demonstrate that the rate of release of capsaicin from Qutenza is linear during the application time. Based on *in vitro* studies, approximately 1% of capsaicin is estimated to be absorbed into the epidermal and dermal layers of skin during one-hour applications. As the amount of capsaicin released from the patch per hour is proportional to the surface area of application, this amounts to an estimated total maximum possible dose for a 1000 cm² area of application of approximately 7 mg. Assuming 1000 cm² of patch area delivers approximately 1% of capsaicin from the patch to a 60 kg person, the maximum potential exposure to capsaicin is approximately 0.12 mg/kg, once every 3 months.

According to the EC Scientific Committee on Food, the average European oral intake of capsaicin is 1.5 mg/day (0.025 mg/kg/day for a 60 kg person) and the highest dietary exposure is 25 to 200 mg/day (up to 3.3 mg/kg/day for a 60 kg person).

Pharmacokinetic data in humans showed transient, low (< 5 ng/ml) systemic exposure to capsaicin in about one third of PHN patients, in 3% of patients with PDN and in no HIV-AN patients following 60-minute applications of Qutenza. No data are available following 30-minute treatments. In general, the proportions of PHN patients with systemic exposure to capsaicin increased with larger treatment areas and with longer treatment durations. The highest concentration of capsaicin detected in patients treated for 60 minutes was 4.6 ng/mL, which occurred immediately after Qutenza removal. Most quantifiable levels were observed at the time of Qutenza removal, with a clear trend towards disappearance by 3 to 6 hours after Qutenza removal. No detectable levels of metabolites were observed in any subject.

A population pharmacokinetic analysis of patients treated for 60 and 90 minutes indicated that capsaicin levels in plasma peaked around 20 minutes after Qutenza removal and declined very rapidly, with a mean elimination half-life of about 130 minutes.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, single-dose toxicity, and repeated-dose toxicity.

Genotoxicity studies performed with capsaicin show a weak mutagenic response in the mouse lymphoma assay and negative responses in the Ames, mouse micronucleus and chromosomal aberration in human peripheral blood lymphocytes assays.

A carcinogenicity study performed in mice indicates that capsaicin is not carcinogenic.

A reproductive toxicology study conducted in rats showed a statistically significant reduction in the number and percent of motile sperms in rats treated 3 hours/day beginning 28 days before cohabitation, through cohabitation and continuing through the day before sacrifice. Although neither statistically significant nor dose dependent, the Fertility Index and the number of pregnancies per number of rats in cohabitation were reduced in all capsaicin-treated groups.

A teratology study conducted in rabbits did not show any potential for fetotoxicity. Delays in skeletal ossification (reductions in ossified metatarsals) were observed in a rat teratology study at dose levels higher than human therapeutic levels; the significance of this finding in humans is unknown. Peri- and post-natal toxicology studies, conducted in rats do not show potential for reproductive toxicity. Lactating rats exposed to Qutenza daily for 3 hours showed measurable levels of capsaicin in the mothers' milk.

A mild sensitization was seen in a cutaneous sensitization study with guinea pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patch

Matrix:

silicone adhesives
diethylene glycol monoethyl ether
silicone oil
ethylcellulose N50 (E462)

Backing layer:

polyester backing film
printing ink containing Pigment White 6

Removable protective layer:

polyester release liner

Cleansing gel

macrogol 300
carbomer
purified water
sodium hydroxide (E524)

disodium edetate
butylhydroxyanisole (E320)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened sachet: 4 years

After opening sachet: apply Qutenza within 2 hours

6.4 Special precautions for storage

Qutenza cutaneous patch: Store flat in the original sachet and carton. Store below 25°C.

Cleansing gel: Store below 25°C.

6.5 Nature and contents of container

The Qutenza patch is stored in a paper coated aluminium foil sachet with acrylnitrile-acrylic acid copolymer heat seal layer.

Qutenza is available in a kit containing one or two individually sealed Qutenza patches and a 50 g tube of cleansing gel.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Health care professionals should wear nitrile gloves when handling patches and cleansing treatment areas. The use of mask and protective glasses may also be considered, see section 4.2.

Used and unused patches and all other materials that have been in contact with the treated area should be disposed of by sealing them in a polyethylene medical waste bag and placing in an appropriate medical waste container.

7. MARKETING AUTHORISATION HOLDER

Astellas Pharma Europe B.V.
Elisabethhof 19
2353 EW Leiderdorp
Netherlands

8. MARKETING AUTHORISATION NUMBERS

EU/1/09/524/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 may 2009

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMA) <http://www.ema.europa.eu>.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

GP Grenzach Produktions GmbH
Emil-Barell-Strasse 7
D-79639 Grenzach-Wyhlen
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance, as presented in Module 1.8.1. of the Marketing Authorisation Application, is in place and functioning before and whilst the medicinal product is on the market.

Risk Management Plan (RMP)

The MAH shall perform the pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in the RMP presented in Module 1.8.2. of the Marketing Authorisation and any subsequent updates of the RMP agreed by the Committee for Medicinal Products for Human Use (CHMP).

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted:

- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
 - Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached
 - At the request of the European Medicines Agency.
- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

The MAH shall agree the details of an educational programme for health care practitioners with the National Competent Authorities and implement such programme nationally before launch.

This educational programme will include:

- recommendations regarding the general handling and disposal measures for Qutenza
 - administration of capsaicin should only be done under medical supervision
 - because of the risk of accidental exposure, the use of nitrile gloves, is recommended; in addition, the use of a mask and protective glasses may be considered
- instructions regarding the administration of Qutenza
- warnings and precautions, including the need:
 - to monitor blood pressure during the treatment procedure
 - to provide supportive treatment if patients experience increased pain during Qutenza administration

- in patients with unstable or poorly controlled hypertension or recent cardiovascular events: to evaluate, prior to initiating Qutenza treatment, the risk of adverse cardiovascular reactions due to the potential stress of the procedure
- in patients using high doses of opioids and with suspected high opioid tolerance: to put in place an alternative pain reduction strategy prior to initiating Qutenza treatment, as these patients may not respond to oral opioid analgesics when used for acute pain during and following the treatment procedure
- to warn patients about the increased risk for adverse reactions due to temporary changes in sensory function (e.g. heat detection) following administration of Qutenza
- to warn patients about the risk of causal local reactions (e.g. contact dermatitis) and of irritation of the eyes and mucous membranes associated with the cleansing gel of Qutenza.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON OF 1 OR 2 PATCHES

1. NAME OF THE MEDICINAL PRODUCT

Qutenza 179 mg cutaneous patch
capsaicin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 280 cm² cutaneous patch contains a total of 179 mg of capsaicin or 640 micrograms of capsaicin per cm² of patch (8% w/w).

3. LIST OF EXCIPIENTS

Patch

Matrix:

silicone adhesives
diethylene glycol monoethyl ether
silicone oil
ethylcellulose N50 (E462)

Backing layer:

polyester backing film
printing ink containing Pigment White 6

Removable protective layer:

polyester release liner

Cleansing gel

macrogol 300
carbomer
purified water
sodium hydroxide (E524)
disodium edetate
butylhydroxyanisole (E320)

See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Each carton contains 1 sachet containing 1 cutaneous patch and 1 tube of cleansing gel (50 g).

Each carton contains 2 sachets, each containing 1 cutaneous patch and 1 tube of cleansing gel (50 g).

5. METHOD AND ROUTE OF ADMINISTRATION

Cutaneous use.

Read the package leaflet before use.

Instructions for use

1. Nitrile gloves should be worn when handling patches and cleansing treatment areas
2. Outline treatment area. Clip excessive hair. Clean treatment area.

If topical anaesthetic is used prior to patch application proceed with 3, else move to 5.

3. Apply topical anaesthetic to treatment area. Wait up to 60 minutes, or according to product's instructions for use.
4. Remove anaesthetic. Gently clean with soap and water and dry thoroughly.
5. Cut patch to match treatment area size. Place non-glossy side up while preparing. Do not remove release liner from the patch until ready for application.
6. Remove patch release liner and apply to the skin. Keep in place for 30 or 60 minutes depending on the location of treatment. Gauze wraps or socks may be used to promote contact between patch and skin.
7. Consider the use of a mask and protective glasses to remove patch and apply cleansing gel afterwards. Wait for one minute and then wipe skin clean with dry gauze. Gently clean treated area with soap and water.

For more detailed instructions, please refer to the Summary of Product Characteristics or the package leaflet.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING, IF NECESSARY

8. EXPIRY DATE

EXP

Use the patch within 2 hours of opening the sachet.

9. SPECIAL STORAGE CONDITIONS

Store flat in the original sachet and carton. Store below 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Dispose of used and unused patches, gauze wipes and all other materials placed in contact with the treated area by sealing in a polyethylene bag and placing in an appropriate medical waste container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Astellas Pharma Europe B.V.
Elisabethhof 19
2353 EW Leiderdorp
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/524/001 1 patch
EU/1/09/524/002 2 patches

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

SACHET OF ONE PATCH

1. NAME OF THE MEDICINAL PRODUCT

Qutenza 179 mg cutaneous patch
capsaicin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 280 cm² cutaneous patch contains a total of 179 mg of capsaicin or 640 micrograms of capsaicin per cm² of patch (8% w/w).

3. LIST OF EXCIPIENTS

Patch

Matrix:

silicone adhesives
diethylene glycol monoethyl ether
silicone oil
ethylcellulose N50 (E462)

Backing layer:

polyester backing film
printing ink containing Pigment White 6

Removable protective layer:

polyester release liner

See the package leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

One cutaneous patch

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

Use the patch within 2 hours of opening the sachet.

9. SPECIAL STORAGE CONDITIONS

Store flat in the original sachet and carton. Store below 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Dispose of used and unused patches, gauze wipes and all other materials placed in contact with the treated area by sealing in a polyethylene bag and placing in an appropriate medical waste container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Astellas Pharma Europe B.V.
Elisabethhof 19
2353 EW Leiderdorp
Netherlands

12. MARKETING AUTHORISATION NUMBERS

EU/1/09/524/001 1 patch
EU/1/09/524/002 2 patches

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

TUBE OF CLEANSING GEL - LABEL

1. NAME OF THE MEDICINAL PRODUCT

Cleansing Gel for use with Qutenza

2. STATEMENT OF ACTIVE SUBSTANCE(S)

3. LIST OF EXCIPIENTS

Contains macrogol 300, carbomer, purified water, sodium hydroxide (E524), disodium edetate and butylhydroxyanisole (E320); See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

50 g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use. See the package leaflet for further information.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store below 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Dispose of cleansing gel tube by sealing in a polyethylene bag along with other used Qutenza components and placing in an appropriate medical waste container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Astellas Pharma Europe B.V.
Elisabethhof 19
2353 EW Leiderdorp
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/524/001 1 patch
EU/1/09/524/002 2 patches

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Qutenza 179 mg cutaneous patch capsaicin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Qutenza is and what it is used for
2. What you need to know before you use Qutenza
3. How to use Qutenza
4. Possible side effects
5. How to store Qutenza
6. Contents of the pack and other information

1. What Qutenza is and what it is used for

Qutenza 179 mg cutaneous patch, Contains capsaicin. Pharmacotherapeutic group: Anaesthetics, Other local anaesthetics.

Qutenza is indicated for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.

Qutenza is used to relieve pain in people without diabetes who have nerve pain due to damage in nerves in the skin. Damaged nerves in your skin may occur as a result of a variety of diseases such as shingles and HIV infection, certain medicines and other conditions. Qutenza can be used either alone or in combination with other medicines that you may take to treat your pain.

2. What you need to know before you use Qutenza

Do not use Qutenza

- if you are allergic to capsaicin, chilli peppers or any other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor before using Qutenza

Do not use Qutenza on any part of your head or face.

Do not use Qutenza on broken skin or open wounds.

Do not touch Qutenza or other materials that have come in contact with the treated areas as it may cause burning and stinging. Do not touch your eyes, mouth or other sensitive areas. Sniffing or inhaling close to the Qutenza patches may cause coughing or sneezing.

It is usual for the skin to sting or become red and burn during and after Qutenza treatment for a short while. Because of the pain, your blood pressure may go up and therefore, your doctor will measure your blood pressure several times during your treatment. If you experience a lot of pain, your doctor will apply local cooling or give you medicine for pain. If you experience very severe pain, ask your doctor to remove the patch.

If you have unstable or poorly controlled high blood pressure or recently had heart problems, your doctor will consider the risk of adverse reactions to your heart or blood pressure due to the potential stress of the procedure before treating you with Qutenza.

If you are using high doses of opioids, you may not respond to oral opioid analgesics when used for acute pain during and following the treatment procedure. In this case, your doctor will use other measures to reduce your pain following Qutenza treatment.

Though no changes have been seen in the function of the nerves in patients treated with Qutenza, small, short-term changes in the ability to feel when something is hot or sharp have been seen after use of capsaicin.

Children and adolescents

Qutenza is not recommended for treatment in patients under 18 years of age.

Other medicines and Qutenza

Qutenza acts locally on your skin and is not expected to influence other medicines. Tell your doctor if you are taking, have recently taken or might take any other medicines.

Qutenza with food and drink

Food or drink are not expected to influence Qutenza as it acts locally on your skin.

Pregnancy and breast-feeding

Qutenza should be used with caution if you are pregnant and/or breastfeeding. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby ask your doctor for advice before taking this medicine.

Driving and using machines

There are no studies of the effects of Qutenza on the ability to drive and use machines. When using Qutenza, only very small amounts of the active substance may be present in the blood stream for a very short time. Therefore, Qutenza is unlikely to have any direct effects on your thinking or your ability to drive or use machinery.

Cleansing gel for Qutenza contains butylhydroxyanisole

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.

3. How to use Qutenza

Qutenza should only be applied by your doctor or by a nurse under the supervision of your doctor.

Qutenza is for use on your skin.

Your doctor will mark the most painful areas on your skin with a pen or marker.

Before placing the Qutenza patches on the skin, the treatment area(s) will be washed with soap and water and dried. Hair in treatment areas will be clipped.

Before placing the Qutenza patches on the skin, your doctor or nurse may apply a numbing gel or cream or give you an oral pain medication to reduce potential stinging. The gel or cream should be removed prior to applying Qutenza and the skin washed and dried thoroughly.

Your doctor or nurse will wear gloves, and sometimes a mask and protective glasses, while handling the Qutenza patches. Do not sniff or inhale close to the Qutenza patches as this may cause coughing or sneezing.

Qutenza may be cut into smaller pieces to fit the treatment area. No more than 4 patches should be used at the same time. Your doctor or nurse will remove the patches after 30 minutes if you're being treated for nerve pain on your feet or 60 minutes if you're being treated for nerve pain on other parts of your body. Do not touch the patch with your hands as it may cause burning and stinging.

Usually you will feel some pain relief on the first day the patch is applied. It may take up to 1-14 days until the full pain relief of Qutenza takes effect. If after that time you still have a lot of pain, please talk to your doctor.

Qutenza therapy may be repeated at 90-day intervals, if necessary.

You may be given pain medicines to take for the pain you experience with Qutenza therapy.

It is common for the skin to sting or become red and burn during Qutenza treatment.

Disposable socks may be worn on top of the Qutenza patches if your feet are being treated.

Sometimes your doctor or nurse may put a bandage on top of the Qutenza patch to keep the patch firmly on your skin.

At the end of the Qutenza treatment your doctor or nurse will clean the treated skin with cleansing gel from a tube supplied with the kit. Cleansing gel will be left on your skin for one minute and then wiped off to remove any remaining medicine that may be left on your skin after treatment. After the cleansing gel has been wiped off, the area will be gently washed with soap and water.

Do not touch your eyes, mouth or other sensitive areas. If you accidentally touch the Qutenza patch or treated skin before cleansing gel is applied it may burn and/or sting. Call your doctor immediately.

Do not attempt to remove the patch yourself. Your doctor or nurse will remove it for you.

Do not take Qutenza patches away from the clinic.

Do not use Qutenza patches at home.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- redness, pain on the area where the patch is applied

Common side effects: may affect up to 1 in 10 people

- itching, bumps, blisters, swelling, dryness on the area where the patch is applied

Uncommon side effects: may affect up to 1 in 100 people

- wheals, prickling sensation, inflammation of the skin, increased sensitivity, inflammation, skin reaction, irritation, bruising on the area where the patch is applied.
- high blood pressure, slowing of the electrical signals in the heart, rapid beating of the heart, abnormal awareness of the beating of the heart, decreased taste, reduced sensations in limbs, burning sensation, eye irritation, cough, throat irritation, nausea, itching, pain in limbs, muscle spasms, shingles, swelling of limbs.

Not known side effects: frequency cannot be estimated from the available data

- second degree burns, accidental exposure (including eye pain, eye and throat irritation and cough)

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store Qutenza

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Qutenza cutaneous patch: Store flat in original sachet and carton. Store below 25°C.

Cleansing gel: Store below 25°C.

After opening sachet, Qutenza should be applied within 2 hours.

Disposal of used and unused Qutenza patches and socks and gloves.

These items may sting your fingers if you touch them. Your doctor or nurse will put them in a polyethylene bag before safely discarding them. Qutenza patches and treatment-related materials should be disposed of properly.

6. Contents of the pack and other information

What Qutenza contains

The active substance is capsaicin. Each 280 cm² patch contains a total of 179 mg of capsaicin or 640 micrograms of capsaicin per cm² of patch (8% w/w).

The other ingredients of the Qutenza cutaneous patch are:

Matrix:

silicone adhesives

diethylene glycol monoethyl ether

silicone oil
ethylcellulose N50 (E462)

Backing layer:

polyester backing film
printing ink containing Pigment White 6

Removable protective layer:

polyester release liner

The Qutenza patch is supplied with a tube of cleansing gel, which contains no active substance.

Cleansing gel contains:

macrogol 300
carbomer
purified water
sodium hydroxide (E524)
disodium edetate
butylhydroxyanisole (E320)

What Qutenza looks like and contents of the pack

Qutenza is a cutaneous patch for use on your skin.

Each patch is 14 cm x 20 cm (280 cm²) and consists of an adhesive side containing the active substance and an outer surface backing layer. The adhesive side is covered with a removable, clear, unprinted, diagonally cut, release liner. The outer surface of the backing layer is imprinted with 'capsaicin 8%'.

Each Qutenza carton contains 1 or 2 sachets and 1 tube of cleansing gel (50 g). Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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Manufacturer responsible for batch release:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

The following information is intended for medical or healthcare professionals only:

A complete Summary of Product Characteristics (SPC) is provided with this leaflet.