

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. See section 4.

What is in this leaflet

1. What Qutenza is and what it is used for
2. What you need to know before Qutenza is used
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 contains capsaicin and belongs to a group of medicines called anaesthetics. Qutenza is indicated for the treatment of peripheral neuropathic pain in adults either alone or in combination with other medicines for the treatment of pain.

Qutenza is used to relieve pain in people who have nerve pain due to damaged nerves in the skin. Damaged nerves in your skin may occur as a result of a variety of diseases such as shingles, HIV infection, diabetes, certain medicines and other conditions. You may experience pain relief between 1 and 3 weeks after treatment.

2. What you need to know before Qutenza is used

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 as it may cause irritation and pain. Sniffing or inhaling close to the Qutenza patches may cause coughing, throat irritation 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.

Generally small, short-term changes in the ability to feel when something is hot or sharp have been seen after use of capsaicin.

If you have unstable or poorly controlled high blood pressure or had heart problems, your doctor will consider the risk of side effects 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.

Children and adolescents

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

Other medicines and Qutenza

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

Pregnancy and breast-feeding

Qutenza should be used with caution if you are pregnant. You should discontinue breastfeeding before treatment with Qutenza is started. 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 ability to concentrate 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.

No more than 4 patches should be used at the same time.

Qutenza is for use on your skin.

Your doctor or nurse 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 medicine 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 may 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. 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.

It may take between 1 to 3 weeks before you experience pain relief with Qutenza. 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. If you experience insufficient pain relief or pain returns earlier, please consult your doctor.

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.

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

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 take Qutenza patches away from the clinic.

Do not use Qutenza patches at home.

.

If Qutenza is used longer than it should

Overdosing is unlikely to occur. However, if Qutenza is applied longer than it should you might experience severe application site reactions like pain, redness and itching.

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.

Contact your doctor straightaway if the following effects happen:

- If you feel that your heart is beating too fast, too slow or is beating abnormally.
 - Uncommon: may affect up to 1 in 100 people
- Deep redness on the area where the patch is applied, blistering/oozing of the skin, skin which becomes very painful to touch, swollen, wet or shiny. In a small number of cases, these may be signs of a second degree burn and need urgent attention.
 - Frequency not known: frequency cannot be estimated from the available data

Tell your doctor if the following side effects occur or get worse:

Very common: may affect more than 1 in 10 people

- Redness or pain on the area where the patch is applied which lasts for more than a day.

Common: may affect up to 1 in 10 people

- Itching, bumps, blisters, swelling, dryness on the area where the patch is applied
- Burning sensation, high blood pressure, cough, nausea, itching, pain in limbs, muscle spasms, swelling of limbs.

Uncommon: may affect up to 1 in 100 people

- Wheals, prickling sensation, inflammation, increased or decreased skin sensation, skin reaction, irritation, bruising on the area where the patch is applied.
- Decreased taste, reduced sensations in limbs, eye irritation, throat irritation, shingles.

Not known: frequency cannot be estimated from the available data

- 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. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

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 the sachet, Qutenza should be applied within 2 hours.

Disposal of used and unused Qutenza patches.

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

Polyethylene Terephthalate (PET) Film, inner side siliconized printing ink containing Pigment White 6

Removable protective layer (release liner)

polyester film, fluoropolymer-coated

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 and Manufacturer

Grünenthal GmbH
Zieglerstraße 6
52078 Aachen
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien

S.A. Grünenthal N.V.
Lenneke Marelaan 8
1932 Sint-Stevens-Woluwe
België/Belgique/Belgien
Tél/Tel: + 32 (0)2 290 52 00
beinfo@grunenthal.com

Lietuva

UAB "STADA – Nizhpharm – Baltija"
Tel: +370 5 2603926

България

STADA Pharma Bulgaria EOOD
25A, Cherni vrah Blvd, fl.4
1421 Sofia, Bulgaria
Тел.: +359 29624626

Česká republika

STADA PHARMA CZ s.r.o.
Tel: +420 257888111

Danmark

Grünenthal Denmark ApS
Tlf: +45 8888 3200

Deutschland

Grünenthal GmbH
Zieglerstr. 6
DE-52078 Aachen
Tel: + 49 241 569-1111
service@grunenthal.com

Eesti

UAB “STADA – Nizhpharm – Baltija“
Leedu
Tel: +370 5 2603926

Ελλάδα

BIANEE A.E.
Οδός Τατοΐου
GR-146 71 Νέα Ερυθραία
Τηλ: + 30 210 8009111-120
mailbox@vianex.gr

España

Grünenthal Pharma, S.A.
C/Dr. Zamenhof, 36
E-28027 Madrid
Tel: +34 (91) 301 93 00

France

Laboratoires Grünenthal SAS
Immeuble Eurêka
19 rue Ernest Renan
CS 90001
F- 92024 Nanterre Cedex
Tél: + 33 (0)1 41 49 45 80

Luxembourg/Luxemburg

S.A. Grünenthal N.V.
Lenneke Marelaan 8
1932 Sint-Stevens-Woluwe
België/Belgique/Belgien
Tél/Tel: + 32 (0)2 290 52 00
beinfo@grunenthal.com

Magyarország

Hemopharm GmbH
Németország
Tel.: +49 61729689

Malta

Grünenthal GmbH
Il-Ġermanja
Tel.: +49-241-569-0

Nederland

Grünenthal B.V.
De Corridor 21K
NL-3621 ZA Breukelen
Tel:+31 (0)30 6046370
info.nl@grunenthal.com

Norge

Grünenthal Norway AS
Tlf: +47 22 99 60 54

Österreich

Grünenthal GmbH
Campus 21, Liebermannstraße A01/501
2345 Brunn am Gebirge
Tel: +43(0)2236 379 550-0

Polska

STADA Poland Sp. Z.o o.
Tel.: +48 227377920

Portugal

Grünenthal, S.A.
Alameda Fernão Lopes, 12-8.º A
P-1495 - 190 Algés
Tel: +351 / 214 72 63 00

Hrvatska

STADA d.o.o..
Hercegovačka 14
10 000 Zagreb
Tel: +385 1 37 64 111

Ireland

Grünenthal Pharma Ltd
4045 Kingswood Road,
Citywest Business Park
IRL – Citywest Co., Dublin
Tel: +44 (0)870 351 8960
medicalinformationie@grunenthal.com

Ísland

Vistor hf.
Sími: +354 535 7000

Italia

Grünenthal Italia S.r.l.
Tel: +39 02 4305 1

Κύπρος

BIANEE A.E.
Οδός Τατοΐου
GR-146 71 Νέα Ερυθραία-Ελλάδα
Τηλ: + 30 210 8009111-120
mailbox@vianex.gr

Latvija

UAB “STADA – Nizhpharm – Baltija“
Lietuva
Tel: +370 5 2603926

România

S.C. STADA M&D S.R.L.
Spatiul Independentei 1b, sectorul 4
Bucuresti
Tel: +40 213160640

Slovenija

STADA d.o.o
Dunajska cesta 156
1000 Ljubljana
Tel: + 386 1589 6710

Slovenská republika

STADA PHARMA Slovakia, s.r.o.,
Tel: +421 252621933

Suomi/Finland

Grünenthal Finland Oy
Puh/Tel: +358 44 240 9190

Sverige

Grunenthal Sweden AB
Tel: +46 (0)8 643 40 60

United Kingdom

Grünenthal Ltd
1 Stokenchurch Business Park
Ibstone Road, HP14 3FE – UK
Tel: +44 (0)870 351 8960
medicalinformationuk@grunenthal.com

This leaflet was last revised in

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.