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Patient information leaflet for QUTENZA

SCHEDULING STATUS

S 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM QUTENZA

QUTENZA Cutaneous Patch (capsaicin 179 mg) and Cleansing gel

Read all of this leaflet carefully before you start using QUTENZA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **QUTENZA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 is a cutaneous patch for use on your skin.

QUTENZA contains capsaicin and belongs to a group of medicines called anaesthetics.

QUTENZA is used to relieve pain in patients who have nerve pain due to damage in nerves in the skin, due to shingles and HIV infection.

2. What you need to know before you use QUTENZA

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

Do not use QUTENZA:

if you are allergic (hypersensitive) to capsaicin, chilli peppers or any other ingredients in **QUTENZA** cutaneous patch (see section 6).

Warnings and precautions**Take special care with 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.

If you experience a lot of pain, your doctor will apply local cooling or give you medicine for pain.

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 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.

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

Always tell your healthcare provider if you are taking, any other medicine. (This includes complementary or traditional medicines.)

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Pregnancy and breastfeeding

You should not use **QUTENZA** if you are pregnant. **QUTENZA** must be kept away from contact with babies.

Mothers must not breastfeed their babies on the day of application.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Driving and using machines

When **QUTENZA** has been applied to your hands or feet, changes in sensation may impair your ability to drive or to use machines.

Important information about some of the ingredients of the cleansing gel for QUTENZA

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

Do not share medicines prescribed for you with any other person.

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 will apply a numbing gel or cream to reduce stinging.

Your doctor or nurse will wear gloves to prepare the **QUTENZA** patches for you.

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.

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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.

If you use QUTENZA longer than you should

Since a doctor or a nurse under the supervision of your doctor will administer QUTENZA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

QUTENZA can have side effects.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects

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

Less frequent side effects

- 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.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist immediately.

Not all side effects reported for QUTENZA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using QUTENZA, please consult your health care provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **QUTENZA**.

5. How to store QUTENZA

QUTENZA cutaneous patch: Store flat in original sachet and carton. Store at or below 25 °C.

Cleansing gel: Store at or below 25 °C.

Do not use **QUTENZA** after the expiry date printed on the carton after EXP. The expiry date refers to the last day of that month.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

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 polythene bag before

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safely discarding them. **QUTENZA** patches and treatment-related materials should be disposed of properly.

6. Content 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 µg of capsaicin per cm² of patch (8 % w/w).

The other ingredients of the **QUTENZA** cutaneous patch are:

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

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: butylhydroxyanisole (E320), carbomer, disodium edentate, macrogol 300 purified water, sodium hydroxide (E524)

What QUTENZA looks like and contents of the pack

QUTENZA 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 %.

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.

Holder of Certificate of Registration

Adcock Ingram Limited

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South Africa

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