

#### Package leaflet: Information for the user

#### QINLOCK 50 mg tablets ripretinib

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

### 1. What QINLOCK is and what it is used for

QINLOCK is a cancer medicine containing the active substance ripretinib, a protein kinase inhibitor. Protein kinase inhibitors are used to treat cancer by stopping the activity of certain proteins that are involved in the growth and spread of cancer cells.

QINLOCK is used to treat **adults** with **gastrointestinal stromal tumour (GIST)**, a rare type of **cancer of the digestive system including the stomach and bowel**, that has:

- spread to other parts of the body or cannot be removed by surgery
- been treated with at least 3 previous cancer medicines, including imatinib.

If you have any questions about how QINLOCK works or why this medicine has been prescribed for you, please ask your doctor.

### 2. What you need to know before you take QINLOCK

**Do not take QINLOCK** if you are **allergic to ripretinib** or **any of the other ingredients** of this medicine (listed in section 6).

#### Warnings and precautions

**Before taking QINLOCK, talk to your doctor or pharmacist if you have or have a history of:**

- high blood pressure. Your doctor will monitor your blood pressure prior to and during treatment with QINLOCK and may give you a medicine to treat high blood pressure, if needed.
- heart conditions. Your doctor may perform additional tests to assess how your heart functions prior to and during your treatment with QINLOCK.

- liver or kidney problems.

**When taking QINLOCK, talk to your doctor or pharmacist if:**

- you notice redness, pain, swelling, or blisters on the palms of your hands or soles of your feet. This is a skin problem called palmar-plantar erythrodysesthesia syndrome (PPES). Your doctor may continue your treatment, change your dose or stop your treatment until your condition improves (see section 4).
- you notice unexpected skin changes such as a new wart, open sore or reddish bump that bleeds or does not heal, or a change in size or colour of a mole. QINLOCK may increase the risk of some types of skin cancers (see section 4). Your doctor will check your skin when starting treatment with QINLOCK and routinely during treatment. It is important that you check your skin regularly.

- you have wounds from any recent surgery that aren't healing as expected. QINLOCK may affect the way wounds heal. Your doctor may decide to temporarily stop treatment with QINLOCK a few days before surgery and until your wound has healed after surgery. Your doctor will decide when to start QINLOCK again. It is important that you tell your doctor if you have any planned surgeries in the future.

- you feel tired, short of breath, notice protruding veins in your neck, or have swelling of the abdomen, ankles or lower legs while taking QINLOCK, these may be symptoms of heart failure (see section 4).

- your skin or eyes become more sensitive to sunlight or other forms of light. Do not expose yourself to direct sunlight, sunlamps and other sources of ultraviolet radiation when taking this medicine. You should wear protective clothing, and apply sun cream with high sun protection factor when you are exposed to strong sunlight.

#### Important information for men and women about contraception

QINLOCK can cause harm to your unborn baby. **Do not** become pregnant while taking QINLOCK. Use effective contraception during treatment and for at least 1 week after the final dose of QINLOCK if you are a female of childbearing potential or a male with a female partner of childbearing potential. If using hormonal contraception, add a barrier contraception (such as condoms). See section on 'Contraception, pregnancy, breastfeeding and fertility'.

#### Children and adolescents

**Do not** give this medicine to children and adolescents below 18 years of age because it has not been studied in this age group.

#### Other medicines and QINLOCK

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

QINLOCK can affect the way some medicines work. Also, some medicines can affect the way QINLOCK works.

In particular, **tell your doctor** if you are taking any of the following medicines:

- medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole)
- medicines used to treat bacterial infections (such as erythromycin, clarithromycin, rifampicin)
- medicines used to treat HIV (such as ritonavir, efavirenz, etravirine)
- medicines used for epilepsy or fits (such as phenytoin, carbamazepine, phenobarbital)
- medicines used to treat irregular heartbeats (such as digoxin)
- medicines used to prevent stroke or harmful blood clots (such as dabigatran etexilate)
- medicines used to lower elevated cholesterol (such as rosuvastatin)
- medicines used to reduce blood glucose or to treat diabetes (such as repaglinide or metformin)
- medicines used to treat severe bowel and rheumatic joint inflammation (such as sulfasalazine)
- medicines used to treat cancer (such as paclitaxel or irinotecan)
- medicines used to prevent organ rejection (such as cyclosporine, tacrolimus)
- medicines used to treat low platelet counts in the blood (such as eltrombopag)
- medicines used to treat muscle spasms (such as tizanidine)
- medicines used to relieve anxiety before procedures (such as midazolam)
- herbal preparations used to treat depression and anxiety containing St. John's Wort (*Hypericum perforatum*).

#### QINLOCK with food and drink

**Grapefruit** juice may change the amount of QINLOCK in your body. Drinking grapefruit juice or eating grapefruit is not recommended during treatment with this medicine.

#### Contraception, pregnancy, breast-feeding and fertility

##### Contraception

Both women of childbearing potential and men should use effective contraception during treatment and for at least 1 week after completion of treatment. If hormonal contraception is used, a barrier method (such as condoms) should be added.

##### Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, you should not take this medicine, unless your doctor has decided that treatment with QINLOCK is clearly necessary. Ask your doctor or pharmacist for advice before taking this medicine.

**Do not get pregnant** while you are being treated with QINLOCK.

If you are a male patient with a partner who is either pregnant or who could become pregnant, you must use a barrier method (such as condoms) during sexual intercourse, during treatment and for at least 1 week after completion of treatment. This medicine may harm your unborn baby. If you are a male and your female partner becomes pregnant during your treatment with QINLOCK, tell your doctor right away.

Woman of childbearing potential will have to do pregnancy tests before treatment start with QINLOCK and during treatment.

##### Breastfeeding

**Do not** breast-feed your baby during treatment with QINLOCK and for at least 1 week after completing treatment, as this medicine may cause **serious side effects** in your baby. Tell your doctor if you are breast-feeding or planning to breast-feed.

##### Fertility

QINLOCK may affect fertility in men and women. Ask your doctor for advice before taking QINLOCK.

##### Driving and using machines

QINLOCK does not directly affect your ability to drive or use machines. If you feel unwell or very tired while being treated with QINLOCK you should not drive or operate machinery until you feel safe to do so.

##### QINLOCK contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take QINLOCK

QINLOCK will be prescribed for you by a doctor experienced in using anticancer therapies.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended daily dose is **three 50 mg tablets** (150 mg) once daily. **Take the tablets at the same time each day** with or without food. Swallow the tablets whole with a glass of water and do not chew, split, or crush the tablets. Do not take any tablets that are broken, cracked, or otherwise damaged due to unknown effects of taking tablet that are not whole.

If you have to take certain other medicines at the same time as QINLOCK, your doctor may change your dose to three 50 mg tablets (150 mg) twice daily.

You will usually take QINLOCK as long as you are benefitting from it and not suffering unacceptable side effects (see section 4); however, your doctor may reduce your dose, or may decide to interrupt or stop the treatment temporarily or permanently if necessary.

##### If you have liver or kidney problems

While you are being treated with QINLOCK, your doctor will monitor your liver or kidney function more closely.

##### If you take more QINLOCK than you should

If you have accidentally taken too many tablets, **seek urgent medical attention**.

##### If you forget to take QINLOCK

What to do if you forget to take this medicine, depends on when you remember the dose that has been forgotten. If it is:

- 8 hours or less (4 hours or less for 150 mg twice per day doses) after the time it should have been taken, take the missed dose as soon as you remember. Then take the next dose as usual.
  - more than 8 hours after (more than 4 hours for 150 mg twice per day doses) the time it should have been taken, skip the missed dose. Then take the next dose at the usual time.
- Do not take a double dose to make up a forgotten dose.

##### If you are sick when taking QINLOCK

If you are sick (vomiting) after taking this medicine, **do not** take an additional dose, but carry on as normal. Take your next dose of tablets the next day at the usual time and tell your doctor you have been sick.

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

### 4. Possible side effects

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

#### Serious side effects

**Seek urgent medical attention** if you experience any of the following **serious side effects** (see section 2):

- **Skin problems** (called PPES)  
PPES is a very common side effect when taking this medicine. If you develop:
  - redness, pain, swelling, or blisters on the palms of your hands or soles of your feet, your doctor may continue your treatment, change your dose or stop your treatment until your condition improves.
- **High blood pressure**  
High blood pressure is a very common side effect when taking this medicine. If you develop:
  - headache, feeling of lightheadedness, or dizziness, these may be symptoms of high blood pressure, your doctor may change your dose or stop your treatment until your condition improves.
- **Heart problems (heart failure)**  
Heart failure is a common side effect when taking this medicine. If you feel:
  - very tired, are short of breath, have swollen feet and/or ankles, these may be symptoms of heart problems.

**Talk to your doctor or pharmacist if you experience:**

- **Skin cancer**  
Treatment with QINLOCK may result in certain types of skin cancer such as 'cutaneous squamous cell carcinoma' and 'melanoma'. Tell your doctor if you notice any skin changes during treatment including a new wart, open sore or reddish bump that bleeds or does not heal, or a change in size or colour of a mole. Your doctor will check your skin when starting treatment with QINLOCK and routinely during treatment (see section 2).
- **Very common side effects** (may affect more than 1 in 10 people):
  - feeling sick (nausea)
  - constipation
  - diarrhoea
  - being sick (vomiting)
  - joint pain
  - headache
  - shortness of breath
  - blood tests showing increased levels of bilirubin, a substance produced by the liver
  - blood tests showing increased levels of lipase, an enzyme involved in digestion
  - blood tests showing decreased levels of phosphate
  - tiredness
  - hair loss
  - muscle ache or pain
  - weight loss
  - muscle spasms
  - dry skin
  - back pain
  - cough
  - swelling in hands and lower legs
  - pain in hands or feet
  - itching
  - non-cancerous skin lesions

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

- sores in mouth
- belly (abdominal) pain
- peripheral nerve impairment (numbness and tingling in feet or hands, burning, stabbing or shooting pain in affected areas, loss of balance and co-ordination, and muscle weakness, especially in the feet)
- skin reactions such as flaking and inflammation of the skin, rash characterised by a flat, red area on the skin that is covered with small bumps or acne
- abnormal liver test (possible liver damage shown by blood test)
- depression
- underactive thyroid gland
- weakness
- chest pain
- rapid heart rate

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. How to store QINLOCK

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 and the bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package and keep the bottle tightly closed in order to protect from light and moisture.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What QINLOCK contains

- The active substance is ripretinib. Each tablet contains 50 mg of ripretinib.
- The other ingredients are crospovidone (E1202), hypromellose acetate succinate, lactose monohydrate, magnesium stearate (E470b), microcrystalline cellulose (E460), and colloidal hydrated silica (E551) (see section 2 "QINLOCK contains lactose").

#### What QINLOCK looks like and contents of the pack

QINLOCK tablets are white to off-white, oval in shape, and debossed with 'DC1' on one side.

Each bottle is child-resistant and contains 30 or 90 tablets and a desiccant. The bottles are provided with aluminium foil/polyethylene (PE) tamper evident seal. The desiccant is a moisture absorbing material filled in a small container to protect the tablets from moisture. Always keep the desiccant pouch in the bottle and do not eat it.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

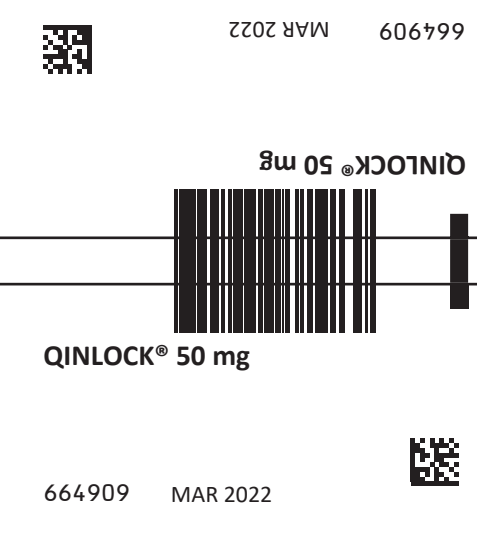
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#### Manufacturer

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