

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **QINLOCK™ Ripretinib Tablets**

Read this carefully before you start taking **QINLOCK** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **QINLOCK**.

Serious Warnings and Precautions

QINLOCK can cause:

- Serious heart problems like heart failure
- High blood pressure
- Serious skin problems:
 - New skin cancers (squamous cell carcinoma or melanoma).

The symptoms are listed in the 'Serious side effects and what to do about them' table. It is found later in this leaflet.

What is QINLOCK used for?

QINLOCK is used to treat adults with gastrointestinal stromal tumor (GIST), which is a type of soft tissue cancer (sarcoma). The cancer must have been treated before with other cancer drugs for GIST including imatinib, sunitinib, and regorafenib.

How does QINLOCK work?

QINLOCK helps slow down the growth of cancer cells in your body.

What are the ingredients in QINLOCK?

Medicinal ingredients: ripretinib

Non-medicinal ingredients: crospovidone, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and silicon dioxide.

QINLOCK comes in the following dosage forms:

Tablets, 50 mg

Do not use QINLOCK if:

- You are allergic to any ingredients in this drug or the bottle.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take QINLOCK. Talk about any health conditions or problems you may have, including if you:

- have or ever had heart problems, like:
 - heart failure and decreased blood flow to your heart.

- have or had high blood pressure.
- have or had skin problems:
 - Avoid strong sunlight, sunlamps, and other sources of ultraviolet (UV) light, such as tanning beds. Your skin may be more sensitive to sunlight while taking QINLOCK and for at least 1 week after stopping treatment with QINLOCK.
 - Use a sunscreen and wear protective clothing that covers your skin when you are exposed to strong sunlight.
 - Skin problems include:
 - New skin cancers (squamous cell carcinoma (SCC) or melanoma).
 - Palmar-plantar erythrodysesthesia syndrome (PPES).
 - Tell your healthcare professional if you have new skin problems or if they change or worsen.
- had or plan to have surgery. Wounds may not heal well during treatment with QINLOCK. If you plan on having the following surgeries:
 - Minor surgery: Your treatment should stop at least three days before and after the surgery.
 - Major surgery: Your treatment should stop at least five days before and after the surgery.
- are younger than 18 years of age.
- have or had an allergic reaction to a drug similar to QINLOCK.

Other warnings you should know about:

Pregnancy and Breastfeeding:

Female Patients

- Avoid becoming pregnant while taking QINLOCK. QINLOCK can harm your unborn baby.
- If you can get pregnant, your healthcare professional will do a pregnancy test before starting treatment.
- You should not take QINLOCK if you are pregnant or if you are still able to get pregnant and are not using highly effective birth control.
- If you can get pregnant, use highly effective birth control methods:
 - for two weeks before your first dose of QINLOCK, while taking QINLOCK, and for at least one menstrual cycle after your final dose.
 - It is not known if QINLOCK can affect your birth control steroid. Use a barrier method of contraception, like condoms, if you are using birth control steroids.
- Tell your healthcare professional right away if you become pregnant or think you are pregnant during treatment with QINLOCK. Your healthcare professional will explain the risks to you.
- It is not known if QINLOCK passes into breast milk. Do not breastfeed during treatment with QINLOCK and for at least two weeks after the final dose. Talk to your healthcare professional about the best way to feed your baby during this time.

Male Patients

- If your partner can get pregnant, use highly effective birth control methods:
 - for two weeks before your first dose of QINLOCK, while taking QINLOCK, and for at least one of your partner's menstrual cycles after your final dose.
- QINLOCK can harm your fertility. This may affect the ability to have children. Talk to your healthcare professional about ways to maintain your fertility before you start treatment.

Check-Ups and Testing: You will have regular visits with your healthcare professional, before, during and at the end of your treatment. They may check:

- that your heart is working properly.
- your blood pressure.
- your skin health.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

For example, the following may interact with QINLOCK:

- Clarithromycin, used to treat infections
- Indinavir, ritonavir, cobicistat and efavirenz, used to treat HIV infection
- Ketoconazole and itraconazole, used to treat fungal infections
- Rifampicin, used to treat bacterial infections, primarily tuberculosis
- Phenytoin and carbamazepine, used to treat seizures and epilepsy
- St John's Wort, used to treat depression
- Grapefruit juice

How to take QINLOCK:

- Take QINLOCK exactly as your healthcare professional tells you. Check with your healthcare professional if you are not sure.
- Take at the same time each day.
- Take with or without food.
- Swallow tablets whole. Do not chew, split or crush tablets. Do not take tablets if they are broken, cracked or damaged.
- Tell your healthcare professional about any side effects you may have when taking QINLOCK.

Recommended Adult Dose:

- Take 150 mg (three 50 mg tablets) of QINLOCK once daily by mouth, at the same time each day.
- Your healthcare professional will monitor your health. They may interrupt, reduce, stop, or increase your dose. This may occur based on your current health, if you take certain other medications or if you have certain side effects.

Overdose:

If you think you, or a person you are caring for, have taken too much **QINLOCK**, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no symptoms.

Missed Dose:

If you are taking QINLOCK twice a day and a dose is missed or not taken at the usual time:

- If you are less than 4 hours late, take the missed dose as soon as you remember. Take the next dose at your regular time.
- If you are more than 4 hours late, skip the dose for that day. Wait until the regular time for your next dose.
- If you vomit after taking a dose, do not take an additional dose and continue with the next scheduled dose.

If you are taking QINLOCK once a day and your dose is missed or not taken at the usual time:

- If you are less than 8 hours late, take the missed dose as soon as you remember. Take the next dose at your regular time.
- If you are more than 8 hours late, skip the dose for that day. Wait until the regular time for your next dose.
- If you vomit after taking a dose, do not take another dose on that day. Take your next dose on the next day at the usual time.

What are possible side effects from using QINLOCK?

These are not all the possible side effects you may feel when taking QINLOCK. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Hair thinning or hair loss
- Tiredness or weakness
- Nausea
- Constipation
- Abdominal, back or joint pain
- Muscle spasms or pain (myalgia)
- Diarrhea
- Decreased appetite
- Decreased weight
- Heartburn
- Mouth sores
- Vomiting
- Headache
- Fever
- Dry or itchy skin
- Dizziness
- Swelling

QINLOCK can cause abnormal blood test results. Your healthcare professional will do some tests before, during and after your treatment. More frequent tests might be needed. They will tell you if your test results are abnormal and if you need treatment.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling		√ (even if you have no symptoms)	√ (if severe)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
in your ankles and legs, racing pulse or heart palpitations			
Palmar-plantar erythrodysesthesia syndrome (PPES): thickening skin, blisters, redness, swelling, and pain on the palms of hands and/or the soles of the feet, tingling or burning, tightness of the skin		√	
COMMON			
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			√
Myocardial ischemia (lack of blood flow to the heart which can lead to heart attack): sudden chest pain, pressure or discomfort, feeling faint, feeling anxious, shortness of breath, irregular heartbeat, nausea, sudden heavy sweating			√
Squamous cell carcinoma, melanoma (skin cancers and disorders): Rash, new or changing skin lesion, thickening of skin, rough scaly patches of skin, open sores, new or changing skin colour.		√	
RARE			
Hypersensitivity (allergic reaction): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, watery eyes			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store QINLOCK in the original container at room temperature (15°C to 25°C).

Keep out of reach and sight of children.

If you want more information about QINLOCK:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or by calling the Importer and Distributor Medison Pharma Canada Inc. at 1-800-696-1341

This leaflet was prepared by Deciphera Pharmaceuticals, LLC

Last Revised July 09, 2024