

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

## **QINLOCK 50 mg**

### **Tablets**

**Active ingredient:** Ripretinib 50 mg

**Inactive and allergenic ingredients:** see Section 6 "Further Information".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine.

If you have further questions, consult with the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

QINLOCK is intended for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST), who have received prior treatment with three or more kinase inhibitors, including imatinib.

**Therapeutic group:** protein kinase inhibitors.

### **2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

You are sensitive (allergic) to ripretinib or to any of the additional ingredients contained in the medicine (see Section 6).

#### **Special warnings regarding the use of the medicine**

Before treatment with QINLOCK tell the doctor about all of your medical conditions, including if you:

- have suffered in the past from a skin problem called palmar-plantar erythrodysesthesia syndrome
- have high blood pressure
- have heart problems
- have had or plan to have surgery
- are pregnant or planning to become pregnant (see "Pregnancy, breastfeeding and fertility")
- are breastfeeding or planning to breastfeed (see "Pregnancy, breastfeeding and fertility").

#### **Special warnings regarding sensitivity to light (photosensitivity):**

Your skin may be sensitive to sunlight or to other forms of light during treatment with QINLOCK. Avoid or limit exposure to direct sunlight, sunlamps and other sources of ultraviolet radiation during treatment and for at least 1 week after stopping treatment with QINLOCK. Use sunscreen and wear clothes that cover your skin if you need to be out in the sun.

## **Special warnings regarding contraception for men and women of childbearing potential:**

QINLOCK can harm the unborn baby. **Do not become pregnant** during treatment with QINLOCK.

If you are a female of childbearing potential or a male with a female partner of childbearing potential, use effective contraception during treatment and for at least 1 week after the final dose of QINLOCK. If you are using hormonal contraception, add a barrier method of contraception (such as condoms). See Section on "Pregnancy, breastfeeding and fertility".

## **Children and adolescents**

Do not use this medicine in children and adolescents under the age of 18.

There is no information regarding the safety and efficacy of the use of this medicine in children and adolescents under the age of 18.

## **Tests and follow-up**

- The attending doctor will perform a skin examination before starting treatment and periodically during treatment.
- The attending doctor will monitor your blood pressure during treatment.
- The attending doctor will perform tests to assess heart function (heart failure) before and during treatment.
- Women of childbearing potential must take a pregnancy test before starting treatment and during treatment.

## **Drug interactions**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, report to the doctor if you are taking any medication from this list or any other medication:

- Certain medicines used to treat fungal infections, such as itraconazole.
- Antibiotics (used to treat bacterial infections), such as rifampin.
- Medicines used to treat HIV, such as efavirenz.
- Avoid using the medicine in combination with strong or moderate CYP3A4 inducers.

## **Use of the medicine and food**

QINLOCK can be taken with or without food.

## **Pregnancy, breastfeeding and fertility**

### Pregnancy

Tell the doctor if you are pregnant, think you may be pregnant or are planning to become pregnant. QINLOCK may harm the unborn baby. Females of childbearing potential must use effective contraception during treatment with QINLOCK and for at least 1 week after the final dose of QINLOCK.

Talk to the attending doctor about the most suitable methods of contraception for you during QINLOCK treatment.

### Males with a female partner of childbearing potential

Use effective contraception during QINLOCK treatment and for at least 1 week after the final dose of QINLOCK.

Immediately inform your doctor if your female partner becomes pregnant during your treatment with QINLOCK.

### Breastfeeding

Tell the doctor if you are breastfeeding or planning to breastfeed. It is not known whether QINLOCK passes into breast milk.

Do not breastfeed during treatment with QINLOCK and for at least 1 week after the final dose of QINLOCK.

### Fertility

QINLOCK may affect fertility in males, which may affect the ability to have children. Consult the doctor before starting treatment with QINLOCK.

### **Driving and operating machinery**

QINLOCK does not directly affect the ability to drive or operate machinery. If you feel unwell or very tired during treatment, you should not drive or operate machinery until you feel safe to do so.

### **Important information about some of the ingredients of the medicine**

#### **QINLOCK contains lactose**

If you have been told by the doctor that you have an intolerance to certain sugars (such as lactose), consult the doctor before starting treatment.

## **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use this preparation according to the doctor's instructions. You should check with the doctor or pharmacist if you are unsure about the dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only.

Usually, the recommended dose is three 50 mg tablets (150 mg) once daily, **at the same time each day**, with or without food.

If you suffer from side effects during treatment, your doctor may decide to stop the treatment, temporarily or permanently.

**Do not exceed the recommended dose.**

#### **Method of administration**

Swallow the tablets whole with a glass of water.

#### **If you accidentally took a higher dose**

If you have taken an overdose or a child has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room, and bring the package of medicine with you.

#### **If you forgot to take QINLOCK**

- If you missed a QINLOCK dose, and no more than 8 hours have passed since the time of the missed dose, take the missed dose as soon as you remember. The next dose should be taken at the usual time.
- If you missed a QINLOCK dose, and more than 8 hours have passed since the time of the missed dose, the missed dose should not be taken. The next dose should be taken at the usual time.

Do not take a double dose to make up for a forgotten dose.

#### **If you suffer from vomiting**

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If you vomit at any stage after taking QINLOCK, **do not** take an additional dose. Take the next dose the following day as planned, at the usual time, and inform the doctor regarding this matter.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment or reduce the dosage of the medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of this medicine, consult the doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, the use of QINLOCK may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

##### **Serious side effects**

**Tell the doctor immediately** if you experience any of the following serious side effects:

##### **A skin problem called palmar-plantar erythrodysesthesia syndrome (PPES):**

Skin problems are common with this treatment, and can sometimes be severe.

If you develop the following symptoms: severe rash, redness, pain, blisters, bleeding or swelling on the palms of the hands or soles of the feet, tell the doctor immediately.

##### **Skin cancer**

Treatment with QINLOCK may cause certain types of skin cancer, such as cutaneous squamous cell carcinoma or melanoma. Talk to the doctor about your risk for these types of cancer.

Check your skin and contact the doctor right away if you notice any skin changes, including a:

- new wart
- sore or bump that bleeds or does not heal
- change in size or color of a mole

##### **High blood pressure (Hypertension):**

High blood pressure is a common side effect with this treatment, and can be serious.

##### **Heart problems (heart failure):**

Heart failure can be serious and can sometimes lead to death.

Tell the doctor if you experience the following symptoms during QINLOCK treatment:

- Tiredness
- Swelling of the abdomen, legs or ankles
- Shortness of breath
- Protruding neck veins

**Wound healing problems:**

As a result of the use of QINLOCK, new wounds may not heal well. Tell the doctor if you intend to undergo surgery before or during the QINLOCK treatment. In case of a planned surgery, the doctor should tell you when to stop taking QINLOCK, and when to resume treatment after the surgery.

**Risk of sensitivity to sunlight (photosensitivity)**

See "Special warnings regarding the use of the medicine".

**Very common side effects** (effects that appear in more than 1 out of 10 users):

- hair thinning or hair loss
- nausea
- constipation
- diarrhea
- vomiting
- tiredness
- abdominal pain
- muscle pain
- loss of appetite
- palmar-plantar erythrodysesthesia syndrome (PPES)
- dry skin
- itching
- fatigue
- peripheral edema
- weakness
- mouth sores
- joint pain
- muscle spasms
- weight loss
- headache
- high blood pressure (Hypertension)
- shortness of breath
- prolonged partial thromboplastin time
- increased INR
- decreased neutrophil count
- increased lipase levels
- decreased phosphorous levels
- increased triglyceride levels
- decreased calcium levels
- increased blood bilirubin levels
- increased CPK
- decreased sodium levels
- increased creatinine levels
- increased serum amylase levels
- increased ALT levels

**Common side effects** (effects that appear in 1-10 out of 100 users):

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- cardiac arrest
- heart attack
- acute coronary syndrome
- peripheral sensory neuropathy
- dermatitis acneiform
- rash

**If a side effect has appeared, if one of the side effects worsens or if you experience a side effect not specified in the leaflet, you should consult the doctor.**

### **Reporting of side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting of side effects and adverse events associated with medications" which is located on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) and refers to the online form for reporting side effects, or by accessing the link: <https://sideeffects.health.gov.il>

## **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine and every other medicine should be kept in a closed place, out of the sight and reach of children and/or infants, thereby preventing poisoning. Do not induce vomiting without explicit instruction from a doctor.
- Do not use the medicine after the expiry date (exp. date) which appears on the packaging/bottle. The expiry date refers to the last day of that month.

### **Storage conditions**

- Store below 25°C. Store in the original packaging to protect from light and moisture.
- Do not use this medicine if you notice that the package is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

## **6. FURTHER INFORMATION**

**In addition to the active ingredient, the medicine also contains:**

microcrystalline cellulose, lactose monohydrate, Hypromellose acetate succinate (HPMCAS-HG), crospovidone, silicon dioxide, magnesium stearate.

**What the medicine looks like and what the package contains:**

The tablet is white to creamy-white in color, oval in shape, with a 'DC1' printed on one side. QINLOCK is available in bottles of 90 tablets.

The packaging contains a desiccant packet to protect the medicine. Do not remove the moisture absorber from the bottle.

**License holder's name and address:**

Medison Pharma Ltd., 10 Hashiloah Street, Petah Tikva. P.O.B. 7090, Israel.

**Manufacturer's name and address:**

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Deciphera Pharmaceuticals, LLC, 200 Smith Street, Waltham, MA, USA.

Revised in July 2025

**Registration number of the medicine in the National Drug Registry of the Ministry of Health: 171-40-36884-99.**