

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using QINLOCK?

QINLOCK contains the active ingredient ripretinib. QINLOCK is used to treat people with advanced gastrointestinal stromal tumours (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. For more information, see Section [1. Why am I using QINLOCK?](#) in the full CMI.

2. What should I know before I use QINLOCK?

Do not use if you have ever had an allergic reaction to ripretinib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant, or are breastfeeding.

For more information, see Section [2. What should I know before I use QINLOCK?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with QINLOCK and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use QINLOCK?

- The usual dose of QINLOCK is 150 mg (three 50 mg tablets) taken orally once daily.
- More instructions can be found in Section [4. How do I use QINLOCK?](#) in the full CMI.

5. What should I know while using QINLOCK?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using QINLOCK.• Use sunscreen with high sun protection factor and wear protective clothing (long sleeves and hat) that covers your skin when exposed to strong sunlight.
Things you should not do	<ul style="list-style-type: none">• Do not go out in strong sunlight or use sunlamps or other sources of ultraviolet (UV) light, such as tanning beds.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how QINLOCK affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.

For more information, see Section [5. What should I know while using QINLOCK?](#) in the full CMI.

6. Are there any side effects?

Common side effects include hair loss and hair thinning, tiredness, nausea, abdominal pain, constipation, muscle pain (myalgia), diarrhoea, decreased appetite, redness or thickening skin of the hands and/or feet, and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems

QINLOCK[®] (kin-lok)

Active ingredient(s): *ripretinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using QINLOCK. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using QINLOCK.**

Where to find information in this leaflet:

1. [Why am I using QINLOCK?](#)
2. [What should I know before I use QINLOCK?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use QINLOCK?](#)
5. [What should I know while using QINLOCK?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using QINLOCK?

QINLOCK contains the active ingredient ripretinib. QINLOCK is a kinase inhibitor which slows down the growth or spread of tumour cells.

QINLOCK is used to treat people with advanced gastrointestinal stromal tumours (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. GIST is a cancer of the stomach and bowels.

2. What should I know before I use QINLOCK?

Warnings

Do not use QINLOCK if:

- you are allergic to ripretinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition. See additional information under [Section 3. What if I am taking other medicines?](#)
- have high blood pressure
- have or had a history of skin problems
 - new skin cancers (cutaneous squamous cell carcinoma (SCC) or melanoma)
 - palmar-plantar erythrodysesthesia syndrome (PPES)
- have any heart conditions
- have skin or eyes that become more sensitive to sunlight or other forms of light
- plan to have any surgical procedures or have had recent surgery
- have wounds from any recent surgery that aren't healing as expected
- have a history of liver or kidney problems

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under [Section 6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Tell your doctor immediately if you become pregnant.

QINLOCK may harm your unborn baby.

If you are a woman who is able to become pregnant:

- Your healthcare provider may perform a pregnancy test before you start treatment with QINLOCK.
- Use effective birth control (contraception) during treatment with QINLOCK and for at least 1 week after the last dose of QINLOCK if you are:
 - a woman who is able to become pregnant.
 - a man with a female partner who is able to become pregnant.
- Talk to your healthcare provider about birth control methods that may be right for you. If hormonal contraception is used, a barrier method (such as condoms) should be added

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if QINLOCK passes into breast milk. Do not breastfeed during treatment with QINLOCK and for at least 1 week after your last dose of QINLOCK.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with QINLOCK and affect how it works.

Medicines that may increase the effect of QINLOCK include:

- ketoconazole, a medicine to treat fungal infections
- itraconazole, a medicine to treat fungal infections
- ritonavir, a medicine to treat HIV infection
- indinavir, a medicine to treat HIV infection
- clarithromycin, a medicine to treat infections

Medicines that may decrease the effect of QINLOCK include:

- rifampin, a medicine to treat bacterial infections such as tuberculosis (TB)
- efavirenz, a medicine to treat HIV infection

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or

supplements you are taking and if these affect QINLOCK.

4. How do I use QINLOCK?

How much to take

- The usual dose of QINLOCK is 150 mg (three 50 mg tablets) taken orally once daily.
- QINLOCK tablets should be swallowed whole. Do not chew, split, or crush tablets.
- Do not ingest if tablets are broken, cracked, or otherwise not intact.
- If you vomit after taking a dose of QINLOCK, do not take an extra dose. Take your next dose at your scheduled time.
- Follow the instructions provided and use QINLOCK until your doctor tells you to stop.

When to take QINLOCK

- Take QINLOCK regularly at the same time each day, with or without food.

If you forget to use QINLOCK

QINLOCK should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, if it is within 8 hours of the scheduled dose.

If more than 8 hours have passed, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much QINLOCK

If you think that you have used too much QINLOCK, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you have kidney or severe liver problems

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

5. What should I know while using QINLOCK?

Things you should do

QINLOCK may affect the way wounds heal. Talk to your doctor if you have wounds from any surgery that are not healing as expected. Your doctor may decide to temporarily stop your treatment with QINLOCK until your wound has healed after surgery. Your doctor will decide when to start QINLOCK again. It is also important that you inform your doctor if you have any planned surgery in future.

- Use sunscreen with high sun protection factor and wear protective clothing that covers your skin when exposed to strong sunlight. Your skin or eyes may be more sensitive to sunlight while taking QINLOCK and for at least 1 week after stopping treatment with QINLOCK.
- Follow your doctor's instructions and keep all appointments. You will need regular follow-up to make sure the treatment is working. Your doctor will measure your blood pressure. You will also have blood tests to check for side effects.

Call your doctor straight away if you:

- Become pregnant
 - Are told your blood pressure is high
- Remind any doctor, dentist or pharmacist you visit that you are using QINLOCK.

Things you should not do

- Do not go out in strong sunlight or use sunlamps, or other sources of ultraviolet (UV) light, such as tanning beds. Your skin or eyes may be more sensitive to sunlight and UV light while taking QINLOCK and for at least 1 week after stopping treatment with QINLOCK.
- Do not drink grapefruit juice or eat grapefruit whilst taking QINLOCK.
- Do not take QINLOCK to treat any other complaints unless your doctor tells you to.

- Do not give QINLOCK to anyone else, even if their condition seems similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how QINLOCK affects you.

Looking after your medicine

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
<p>Broad or affecting different parts of the body:</p> <ul style="list-style-type: none"> Tiredness Swelling in arms and/or legs Increased levels of blood bilirubin, which is a pigment produced by the liver. Increased levels can cause possible yellowing of the skin and/or eyes and may indicate liver injury <p>Muscle or pain related:</p> <ul style="list-style-type: none"> Muscle pain, spasms Joint pain <p>Stomach and digestive system related:</p> <ul style="list-style-type: none"> Nausea Abdominal pain Constipation Diarrhoea Loss of appetite, weight loss Vomiting <p>Skin related:</p> <ul style="list-style-type: none"> Hair thinning or hair loss 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<p>phosphate (a chemical in the blood)</p> <ul style="list-style-type: none"> Heart problems (heart failure including symptoms of feeling very tired, have swollen feet and/or ankles, chest pain, difficulty breathing, and/or dizziness, heart pounding or racing) <p>Skin related:</p> <ul style="list-style-type: none"> PPES includes symptoms of redness, pain, blisters/peeling, swelling, or callouses on the palms of your hands or soles of your feet An increased risk of certain types of skin cancer such as 'cutaneous squamous cell carcinoma of skin' and 'melanoma'. It is important to check your skin regularly 	<p>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</p>
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Serious side effects

Serious side effects	What to do
<p>Broad or affecting different parts of the body:</p> <ul style="list-style-type: none"> Anaemia (decreased red blood cells in the blood, which may make you feel tired or short of breath) High blood pressure (headache, feeling of lightheadedness, dizziness) Blood tests showing high blood levels of lipase, an enzyme that breaks down fat Blood tests showing decreased levels of 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What QINLOCK contains

Active ingredient (main ingredient)	Ripretinib
Other ingredients (inactive ingredients)	Crospovidone Hypromellose acetate succinate Lactose monohydrate Magnesium stearate Microcrystalline cellulose Silicon dioxide

Do not take this medicine if you are allergic to any of these ingredients.

What QINLOCK looks like

QINLOCK tablets are white to off-white oval shaped tablets debossed with 'DC1' on one side.

Aust R 327899

Who distributes QINLOCK

Specialised Therapeutics PM Pty Ltd
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