

FRUZAQLA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on 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 FRUZAQLA?

FRUZAQLA contains the active ingredient fruquintinib. FRUZAQLA is used to treat adult patients with colorectal cancer (CRC) that has spread to other parts of the body (metastatic). It is used when other treatments have not worked or when other treatments are not suitable for you.

For more information, see Section [1. Why am I using FRUZAQLA?](#) in the full CMI.

2. What should I know before I use FRUZAQLA?

Do not use if you have ever had an allergic reaction to FRUZAQLA 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, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with FRUZAQLA 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 FRUZAQLA?

- Recommended dose: 5 mg once daily (approximately same time each day) for 21 days (3 weeks), followed by 7 days (1 week) of no medicine.
- FRUZAQLA can be taken with or without food and should be swallowed as a whole capsule.
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- More instructions can be found in Section [4. How do I use FRUZAQLA?](#) in the full CMI.

5. What should I know while using FRUZAQLA?

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|---|--|
| <p>Things you should do</p> | <ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using FRUZAQLA. • If you are pregnant, intending to get pregnant or to father a child, tell your doctor immediately |
| <p>Things you should not do</p> | <ul style="list-style-type: none"> • Do not stop using this medicine without talking to your doctor first. |
| <p>Driving or using machines</p> | <ul style="list-style-type: none"> • Do not drive or operate machinery if you experience symptoms that affect your ability to concentrate and react. |
| <p>Looking after your medicine</p> | <ul style="list-style-type: none"> • Keep the medicine in a cool, dry place where the temperature stays below 30°C. |

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

6. Are there any side effects?

Reduced blood platelets, reduced thyroid activity, weight loss and decreased appetite, high blood pressure, voice change/ hoarseness, diarrhoea, painful dry mouth, mouth sores/ulcers, redness, pain, blisters and swelling of palms/ soles of feet, pain in muscles, bones, joints, chest or neck, protein in urine, weakness, tiredness. Upper respiratory infection, fever, sore throat, cough, pneumonia, low blood cell counts, nosebleeds, throat pain, pancreatic enzyme elevation, hole in stomach, toothache, gum or lip pain, mouth sores, rash. Severely elevated blood pressure, digestive system bleeding (stomach, throat, rectum bowel), severe stomach pain, confusion, seizure, vision change, abnormal liver function test, yellowing skin/white part of eyes, dark coloured urine, burning pain when urinating, right upper stomach pain, nausea, vomiting, bruising, severe cough, trouble breathing, redness/pain in any part body, severe chest pain/ pressure, pain in arm, leg back, neck or jaw, shortness of breath, numbness/weakness of face, arm or leg, confusion, trouble talking or walking, severe headache, dizziness/loss of balance. 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.

FRUZAQLA®

Active ingredient(s): *fruquintinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FRUZAQLA. **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 FRUZAQLA.**

Where to find information in this leaflet:

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

1. Why am I using FRUZAQLA?

FRUZAQLA contains the active ingredient fruquintinib. FRUZAQLA belongs to a group of medicines called antineoplastic (or anti-cancer) agents which are used to treat cancer.

- FRUZAQLA is used to treat adult patients with colorectal cancer (CRC) that has spread to other parts of the body (metastatic). It is used when other treatments have not worked or when other treatments are not suitable for you.
- FRUZAQLA stops tumours from making new blood vessels and therefore slows down the growth of cancer. Blood vessels would usually provide the tumour with nutrients and oxygen.

2. What should I know before I use FRUZAQLA?

Warnings

Do not use FRUZAQLA if:

- you are allergic to fruquintinib, 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:

- take any medicines for any other conditions
- have any other medical conditions including:

- high blood pressure
- bleeding problems or are taking medicines to thin the blood or prevent blood clots
- severe stomach or bowel problems
- liver problems
- kidney problems or have protein in your urine
- skin problems
- recently had severe or persistent headache, trouble with your vision, seizures or fits, or altered mental status such as confusion, memory loss or loss of orientation
- have an infection
- recently had or going to have a surgical procedure or have an unhealed wound
- recently had problems with blood clots in your blood vessels including stroke, heart attack, embolism or thrombosis

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

Tell your doctor if you are pregnant or intend to become pregnant.

FRUZAQLA has not been studied in pregnant women. FRUZAQLA should not be used during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will discuss with

you the potential risks of taking this medicine during pregnancy.

- Women who are able to become pregnant and male patients with female partners who are able to become pregnant should use highly effective contraceptive methods during treatment, and for at least 2 weeks following the last dose of FRUZAQLA. Talk to your doctor about the right methods of contraception for you and your partner.
- Talk to your doctor if you are breastfeeding or intend to breastfeed.
- It is not known whether FRUZAQLA passes into breast milk. You should not breast-feed during treatment with this medicine and for at least 2 weeks following the last dose of FRUZAQLA. Talk to your doctor about the best way to feed your baby during this time.

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 FRUZAQLA and affect how it works. These include:

- rifampicin, a medicine used to treat tuberculosis or other infections
- efavirenz, a medicines used to treat HIV-1 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 FRUZAQLA.

4. How do I use FRUZAQLA?

FRUZAQLA should only be prescribed by a doctor experienced in cancer treatment.

How much to take

- The recommended dose of FRUZAQLA is 5 mg once daily at approximately the same time each day for 21 days (3 weeks), followed by 7 days (1 week) of no medicine. This three weeks on, one week off treatment period is 1 cycle of treatment.
- FRUZAQLA can be taken with or without food and should be swallowed as a whole capsule.
- Your doctor may reduce your dose if necessary.
- Follow the instructions provided and use FRUZAQLA until your doctor tells you to stop.

When to take FRUZAQLA

- FRUZAQLA should be taken once a day at about the same time each day.

If you forget to take FRUZAQLA

If you miss your dose at the usual time and it is almost time for your next dose (less than 12 hours), skip the dose you missed and take your next dose when you are meant to.

If there are more than 12 hours until your next dose, take the dose you missed dose and then take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. This may increase the chance of getting an unwanted side effect.

If you vomit after taking FRUZAQLA, do not take a replacement capsule. Continue to take your next dose at the usual time.

If you use too much FRUZAQLA

If you think that you have used too much FRUZAQLA, 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.

5. What should I know while using FRUZAQLA?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FRUZAQLA.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Use highly effective contraception to prevent pregnancy while you are being treated with FRUZAQLA.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do blood tests and other tests from time to time to monitor your progress and check for side effects. If necessary, your doctor may decide to reduce your dose, temporarily interrupt your treatment or stop it altogether.

Call your doctor straight away if you:

experience:

- very high blood pressure
- severe headache
- severe chest pain

- passing blood in the stools or passing black stools
- passing blood in the urine
- severe stomach (abdominal) pain or stomach pain that does not go away
- coughing/vomiting up blood.
- confusion, seizures (fits)
- changes in vision

Remind any doctor, dentist or pharmacist you visit that you are using FRUZAQLA.

Things you should not do

- Do not stop taking medicine unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they
- have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

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

FRUZAQLA may cause vision disturbances or tiredness in some people.

Do not drive or use machines during treatment if such signs occur.

Looking after your medicine

- Keep in a cool, dry place where the temperature stays below 30°C.
- Keep your capsules in the bottle until it is time to take them. If you take the capsules out of the bottle they may not keep well. Keep the bottle tightly closed. Do not remove desiccant cartridge from the bottle.

Store 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

| Less serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none">● reduced activity of the thyroid gland● weight loss and decreased appetite● high blood pressure● voice changes or hoarseness● diarrhoea● painful or dry mouth, mouth sores or ulcers● abnormal liver function test results● burning or pain when urinating● redness, pain, blisters and swelling of the palms of the hands or soles of the feet● pain in the muscles, bones, joints, chest or neck● protein in your urine | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● weakness and excessive tiredness ● upper respiratory tract infection ● fever ● sore throat ● cough ● pneumonia ● low blood cell counts ● reduced number of blood platelets ● low levels of potassium in blood ● nosebleed ● throat pain ● elevations of pancreatic enzymes ● toothache, gum pain, lip pain or mouth sores ● rash ● delayed healing of a wound | |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> <li data-bbox="204 271 778 663">● Severely elevated blood pressure – symptoms may include severe headache, lightheadedness or dizziness, confusion and severe chest pain <li data-bbox="204 680 778 1184">● Bleeding in the digestive system – symptoms may include passing blood in the stools or passing black stools, passing blood in the urine, stomach pain, coughing/vomiting up blood <li data-bbox="204 1202 778 1706">● Severe stomach and bowel problems – symptoms may include coughing up blood, vomiting blood, severe stomach pain or stomach pain that does not go away, red or black stools <li data-bbox="204 1724 778 2004">● Serious infections – symptoms may include fever, severe cough, trouble breathing, burning or pain when | <p data-bbox="810 271 1385 663">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> |

| Serious side effects | What to do |
|--|------------|
| <p>urinating, redness or pain in any part of the body</p> <ul style="list-style-type: none"> ● Liver problems - symptoms may include yellowing of your skin or the white part of your eyes, dark coloured urine, pain in your right upper stomach-area (abdomen), loss of appetite, nausea, vomiting, bleeding or bruising ● Reversible swelling of the brain (posterior reversible encephalopathy syndrome) - symptoms may include headache, confusion, seizures (fits), changes in vision ● Blood clots in your blood vessels – symptoms may include severe chest pain or pressure, pain in your arms, legs back, neck or jaw, shortness of breath, numbness or weakness | |

| Serious side effects | What to do |
|---|-------------------|
| of your face, arm or leg (especially one side of your body), sudden confusion, trouble talking, or understanding things, trouble walking, severe headache, vision changes, dizziness, loss of balance | |

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 FRUZAQLA contains

| | |
|---|---|
| Active ingredient (main ingredient) | 1 mg or 5 mg fruquintinib |
| Other ingredients (inactive ingredients) | <p>FRUZAQLA 1 mg hard capsules:</p> <ul style="list-style-type: none">● Inactive ingredients: maize starch, microcrystalline cellulose and purified talc● capsule shells contain gelatin, titanium dioxide, tartrazine and sunset yellow FCF.● capsules are imprinted with TekPrint SW-9008 Black Ink (ARTG PI No 2328). <p>FRUZAQLA 5 mg hard capsules:</p> <ul style="list-style-type: none">● Inactive ingredients: maize starch, microcrystalline |

| | |
|--|--|
| Active ingredient (main ingredient) | 1 mg or 5 mg fruquintinib |
| | cellulose and purified talc <ul style="list-style-type: none"> ● capsule shells contain gelatin, titanium dioxide, brilliant blue FCF and allura red AC ● capsules are imprinted with TekPrint SW-9008 Black Ink (ARTG PI No 2328) |

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

What FRUZAQLA looks like

FRUZAQLA 1 mg capsules are an opaque hard gelatin capsule, size 3 (approximate length 16 mm), with a yellow cap and a white body imprinted with “HM013” over “1mg” in black ink (AUST R 422039).

FRUZAQLA 5 mg capsules are an opaque hard gelatin capsule, size 1 (approximate length 19 mm), with a red cap and a white body imprinted with “HM013” over “5mg” in black ink (AUST R 422038).

Who distributes FRUZAQLA

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street
Sydney, NSW 2000
Australia

Telephone: 1800 012 612

www.takeda.com/en-au

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