

PACKAGE LEAFLET

Package leaflet: Information for the patient

FRUZAQLA® 1 mg hard capsules

FRUZAQLA® 5 mg hard capsules

fruquintinib

▼ 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fruzaqla is and what it is used for
2. What you need to know before you take Fruzaqla
3. How to take Fruzaqla
4. Possible side effects
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1. What Fruzaqla is and what it is used for

What Fruzaqla is

Fruzaqla (fru-zahk-la) contains the active substance fruquintinib (froo-kwin-tih-nib).

What Fruzaqla is used for

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.

How Fruzaqla works

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.

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

2. What you need to know before you take Fruzaqla

Do not take Fruzaqla

- if you are allergic to fruquintinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Fruzaqla or anytime during treatment if you have any of the following conditions. Your doctor may give you other medicines in order to prevent

more severe complications and reduce your symptoms. Your doctor may temporarily withhold the next dose of Fruzaqla or stop your treatment with Fruzaqla.

- **high blood pressure.** Your doctor should make sure that your blood pressure is under control before starting and while taking this medicine.
- any **bleeding problems.** Tell your doctor if you had or have bleeding problems or if you are taking warfarin, acenocoumarol, or other medicines to thin the blood to prevent blood clots.
- **infection symptoms:** Tell your doctor if you have fever, severe sore throat or cough.
- **severe stomach and bowel problems** (a hole in your gut wall). If you get severe stomach and bowel problems, talk to your doctor immediately.
- **liver problems:** Your doctor will do blood tests before and during treatment with Fruzaqla to check for liver problems. Tell your doctor if you have yellowing of your skin or the white part of your eyes and dark coloured (tea coloured) urine.
- **kidney problems** (presence of protein in your urine).
- any **skin problems**, which may include redness, pain, swelling, or blisters on the palms of your hands or soles of your feet.
- recently had **severe and persistent headache, visual disturbances, seizures or altered mental status** (such as confusion, memory loss or loss of orientation). If you notice any of these changes, talk to your doctor immediately.
- recently had or are going to have a surgical procedure or have an unhealed wound. Fruzaqla may affect the way your **wounds heal**.
- **recently had problems with blood clots** in your veins and arteries (types of blood vessels), including stroke, heart attack, embolism, or thrombosis.
- **you have or have had an aneurysm** (enlargement and weakening of a blood vessel wall) **or a tear in a blood vessel wall**

Children and adolescents

The safety and efficacy of Fruzaqla in children aged 0 to <18 years have not been established. No data is available.

Other medicines and Fruzaqla

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking medicines used to treat tuberculosis or certain other infections, such as rifampicin , or taking medicines used to treat HIV-1 infection, such as efavirenz.

Taking Fruzaqla with food and drink

Fruzaqla can be taken with or without food and should be swallowed as a whole capsule.

Pregnancy, breast-feeding and fertility

Pregnancy

Fruzaqla has not been studied in pregnant women. Fruzaqla should not be used during pregnancy unless clearly necessary. 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.

Breast-feeding

Tell your doctor if you are breast-feeding or planning to breast-feed. It is unknown if Fruzaqla passes into breast milk, and a risk to neonates/infants cannot be excluded. 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.

Fertility

There are no data on the effects of Fruzaqla on human fertility.

Contraception – for men and women

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.

Driving and using machines

It is unknown whether Fruzaqla changes your ability to drive or use machines. Do not drive or use any tools or machines if you experience symptoms that affect your ability to concentrate and react.

Fruzaqla contains

Tartrazine (E102) and sunset yellow FCF (E110) in 1 mg capsules only. These are colouring agents, which may cause allergic reactions.

Allura red AC (E129) in 5 mg capsules only. This is a colouring agent, which may cause allergic reactions.

3. How to take Fruzaqla

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

Recommended dose

The recommended dose is 5 milligrams (mg) once daily at approximately the same time each day for 21 days (3 weeks), followed by 7 days (1 week) of rest (no medicine). This is 1 cycle of treatment. Fruzaqla can be taken with or without food and should be swallowed as a whole capsule.

How long to take Fruzaqla

Your doctor will check regularly, and you will normally continue to take Fruzaqla as long it is working, and you do not suffer unacceptable side effects.

If you take more Fruzaqla than you should

Tell your doctor immediately if you have taken more than your prescribed dose. You may require medical attention and your doctor may tell you to stop taking Fruzaqla.

If you forget to take Fruzaqla

If there are less than 12 hours until your next dose, skip the missed dose and then take the next one as planned.

If there are more than 12 hours until your next dose, take the missed dose and then take the next one as planned.

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

If you stop taking Fruzaqla

Do not stop taking the medicine unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Depending on how you respond to treatment and possible side effects, your doctor may ask you to change to a lower dose or to temporarily or permanently stop the treatment.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects

Tell your doctor immediately if you notice any of the following serious side effects.

High blood pressure

Tell your doctor if you experience the following symptoms:

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

Bleeding

Fruzaqla can cause severe bleeding in the digestive system such as stomach, throat, rectum or intestine.

Get medical help immediately if you get the following symptoms:

- passing blood in the stools or passing black stools
- passing blood in the urine
- stomach pain
- coughing/vomiting up blood.

Infections

Treatment with Fruzaqla may increase the risk of infections, including serious infections.

Tell your doctor, if you get the following symptoms:

- fever
- severe cough with or without an increase in mucus (sputum) production
- severe sore throat
- trouble breathing
- burning or pain when you urinate
- redness, swelling or pain in any part of the body.

Severe stomach and bowel problems

Treatment with Fruzaqla may lead to gastrointestinal perforation.

Get medical help immediately, if you get the following symptoms:

- vomiting or vomiting blood.
- severe stomach (abdominal) pain or stomach pain that does not go away
- blood in the stool or black stool that looks like tar
- fever or chills
- nausea.

Liver problems

Increased liver enzymes in your blood are common with FRUZAQLA and can also be severe.

Tell your doctor that you get the following symptoms:

- yellowing of your skin or the white part of your eyes
- dark coloured (tea coloured) urine
- pain in your right upper stomach-area (abdomen)
- loss of appetite
- nausea or vomiting
- bleeding or bruising.

Reversible swelling of the brain (posterior reversible encephalopathy syndrome).

Get emergency medical help immediately and call your doctor if you get the following symptoms:

- headache
- confusion, seizures (fits)
- changes in vision with or without high blood pressure.

Other side effects with Fruzaqla may include:

Very common (may affect more than 1 in 10 people):

- reduced number of blood platelets (cells that help blood to clot) may show in your blood tests (thrombocytopenia) – can cause easy bruising or bleeding
- reduced activity of the thyroid gland (hypothyroidism)
- weight loss and decreased appetite (anorexia)
- high blood pressure (hypertension)
- voice changes or hoarseness (dysphonia)
- frequent or loose bowel movements (diarrhoea)
- painful or dry mouth, mouth sores or ulcers (stomatitis)
- abnormal liver function test (increase amounts of the liver enzyme alanine aminotransferase and aspartate aminotransferase)
- increased levels of bilirubin in the blood (abnormal liver function test)
- redness, pain, blisters and swelling of the palms of the hands or soles of the feet (palmar-plantar erythrodysesthesia syndrome)
- bone, muscle, chest, or neck pain (musculoskeletal discomfort)
- joint pain (arthralgia)
- protein in your urine (proteinuria)
- weakness, lack of strength and energy, excessive tiredness and unusual sleepiness (asthenia/fatigue)

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

- infection of the lungs (pneumonia)
- nose and throat (upper respiratory tract) infection
- reduced number of white blood cells may show in your blood tests (leukopenia) – can increase your risk of infection
- reduced number of neutrophils (type of white blood cell) may show in your blood tests (neutropenia) – can increase your risk of infection
- low levels of potassium in blood (hypokalaemia)
- nosebleed (epistaxis)
- throat pain
- bleeding in the digestive system such as stomach, rectum or intestine (gastrointestinal haemorrhage)
- elevations of pancreatic enzymes (pancreatic enzymes increased)
- hole in the gut wall (gastrointestinal perforation)
- toothache, gum, or lip pain (oral pain)
- rash
- mouth sores (mucosal inflammation)

Uncommon (may affect up to 1 in 100 people):

- reversible swelling of the brain (posterior reversible encephalopathy syndrome)
- inflammation of the pancreas (pancreatitis)

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.

Website: 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 Fruzaqla

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 medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

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

6. Contents of the pack and other information

What Fruzaqla contains

Fruzaqla 1 mg hard capsules

- The active substance is fruquintinib. Each hard capsule contains 1 mg fruquintinib.
- The other ingredients are:
 - Capsule fill: maize starch, cellulose, microcrystalline, talc
 - Capsule shell: gelatine, titanium dioxide, tartrazine (E102), sunset yellow FCF (E110)
 - Printing ink: dewaxed shellac, propylene glycol, potassium hydroxide, iron oxide black.

Fruzaqla 5 mg hard capsules

- The active substance is fruquintinib. Each hard capsule contains 5 mg fruquintinib.
- The other ingredients are:
 - Capsule fill: maize starch, cellulose, microcrystalline, talc
 - Capsule shell: gelatine, titanium dioxide, allura red AC (E129), brilliant blue FCF
 - Printing ink: dewaxed shellac, propylene glycol, potassium hydroxide, iron oxide black.

What Fruzaqla looks like and contents of the pack

Fruzaqla 1 mg hard capsules are white with a yellow cap, imprinted with “HM013” over “1mg”.

Fruzaqla 5 mg hard capsules are white with a red cap, imprinted with “HM013” over “5mg”.

Each white bottle contains 21 hard capsules.

Keep the desiccant in the bottle. The white cartridge desiccant is a moisture absorbing material filled in a small container to protect the capsules from moisture.

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