

PATIENT INFORMATION
TRUSELTIQ™ (tru sel tik)
(infigratinib) capsules

What is TRUSELTIQ?

TRUSELTIQ is a prescription medicine used to treat adults with bile duct cancer (cholangiocarcinoma) that has spread or cannot be removed by surgery:

- who have already received a previous treatment, **and**
- whose tumor has a certain type of abnormal “FGFR2” gene.

Your healthcare provider will test your cancer for certain FGFR2 gene abnormalities to make sure that TRUSELTIQ is right for you.

It is not known if TRUSELTIQ is safe and effective in children.

Before taking TRUSELTIQ, tell your healthcare provider about all your medical conditions, including if you:

- have vision or eye problems
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. TRUSELTIQ can harm your unborn baby or cause loss of your pregnancy (miscarriage). You should not become pregnant during treatment with TRUSELTIQ.

Females who can become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with TRUSELTIQ.
- You should use effective birth control during treatment and for 1 month after your final dose of TRUSELTIQ. Talk to your healthcare provider about birth control methods that may be right for you during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during this time.

Males with female partners who can become pregnant:

- You should use effective birth control when sexually active during treatment with TRUSELTIQ and for 1 month after your final dose of TRUSELTIQ.
- are breastfeeding or plan to breastfeed. It is not known if TRUSELTIQ passes into your breast milk. Do not breastfeed during treatment and for 1 month after your final dose of TRUSELTIQ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking TRUSELTIQ with certain other medicines may affect how TRUSELTIQ works.

Especially tell your healthcare provider if you take medicines used to decrease stomach acid and treat heartburn, called proton pump inhibitors (PPIs), H2 blockers, or antacids. You should avoid taking these medicines during treatment with TRUSELTIQ. If you cannot avoid taking H2 blockers or antacids, see **“How should I take TRUSELTIQ?”** for more information on how to take TRUSELTIQ with these medicines.

How should I take TRUSELTIQ?

- Take TRUSELTIQ exactly as your healthcare provider tells you.
- Take your prescribed dose of TRUSELTIQ 1 time each day for 21 days, followed by 7 days off treatment. This is 1 cycle of treatment (28 days). You will repeat this cycle for as long as your healthcare provider tells you to.
- Take TRUSELTIQ at about the same time each day.
- Take TRUSELTIQ on an empty stomach, at least 1 hour before or 2 hours after food.
- Swallow TRUSELTIQ capsules whole with a glass of water.
- **Do not** crush, chew, or dissolve TRUSELTIQ capsules. Tell your healthcare provider if you have problems swallowing capsules whole.
- If you need to take an acid reducer called H2 blocker, take TRUSELTIQ 2 hours before or 10 hours after taking the acid reducer.
- If you need to take an antacid, take TRUSELTIQ 2 hours before or 2 hours after taking the antacid.
- You should not eat or drink grapefruit products during treatment with TRUSELTIQ.
- Your healthcare provider may change your dose of TRUSELTIQ, temporarily stop, or completely stop treatment if you get certain side effects.
- If you miss a dose of TRUSELTIQ, you can take the missed dose within 4 hours on the same day. If more than 4 hours have passed, do not take the dose. Take your regular dose of TRUSELTIQ the next day at the usual time. Do not take more TRUSELTIQ than prescribed to make up for the missed dose.
- If you vomit after taking TRUSELTIQ, **do not** take an extra dose. Take your regular dose of TRUSELTIQ the

next day at the usual time.

What are the possible side effects of TRUSELTIQ?

TRUSELTIQ may cause serious side effects, including:

- **Eye problems.** Certain eye problems are common with TRUSELTIQ but can also be serious. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye), increased tears, and disorders of the retina (an internal part of the eye). You will need to see an eye specialist for a complete eye exam before you begin treatment with TRUSELTIQ, at 1 month, at 3 months, and then every 3 months during treatment with TRUSELTIQ. Your healthcare provider should closely monitor you for eye problems.
 - You should use artificial tear substitutes, hydrating or lubricating eye gels as needed, to help prevent or treat dry eyes.
 - **Tell your healthcare provider right away** if you develop any changes in your vision including blurred vision, during treatment with TRUSELTIQ. You may need to see an eye specialist right away.
- **High phosphate levels in the blood (hyperphosphatemia) and buildup of minerals in different tissues in your body.** Hyperphosphatemia is common with TRUSELTIQ but can also be serious. High levels of phosphate in your blood may lead to buildup of minerals such as calcium in different tissues in your body. Your healthcare provider will check your blood phosphate levels during treatment with TRUSELTIQ.
 - Your healthcare provider may prescribe phosphate lowering therapy or change, interrupt, or stop TRUSELTIQ if needed.
 - Tell your healthcare provider right away if you develop any muscle cramps, numbness, or tingling around your mouth.

The most common side effects of TRUSELTIQ include:

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| • changes in kidney function blood tests | • dry eyes | • constipation |
| • decreased levels of phosphate, sodium, and potassium in the blood | • feeling tired or weak | • stomach-area (abdominal) pain or discomfort |
| • nails separate from the bed or poor formation of the nail | • increased calcium levels in the blood | • dry mouth |
| • mouth sores | • hair loss | • changes in eyelash |
| • changes in liver function blood tests | • increased fat levels (triglyceride) in the blood | • diarrhea |
| • decreased red blood cell, white blood cell, and platelet counts | • increased levels of uric acid in the blood | • decreased protein levels (albumin) in the blood |
| • increased lipase levels (a blood test done to check your pancreas) | • redness, swelling, peeling or tenderness, mainly on the hands or feet ('hand-foot syndrome') | • dry skin |
| | • joint pain | • decreased appetite |
| | • changes in sense of taste | • blurred vision |
| | | • vomiting |

These are not all possible side effects of TRUSELTIQ. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TRUSELTIQ?

- Store TRUSELTIQ at room temperature between 68°F to 77°F (20°C to 25°C).

Keep TRUSELTIQ and all medicines out of the reach of children.

General information about the safe and effective use of TRUSELTIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TRUSELTIQ for a condition for which it was not prescribed. Do not give TRUSELTIQ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

What are the ingredients in TRUSELTIQ?

Active ingredient: infigratinib phosphate

Inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose, lactose monohydrate, magnesium stearate (from vegetable source), and microcrystalline cellulose.

The capsule shells contain: black iron oxide, gelatin, red iron oxide, titanium dioxide, and yellow iron oxide.

The printing ink contains: black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, shellac, and strong ammonia solution.

Manufactured for: QED Therapeutics, Inc. Brisbane, CA 94005

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For more information call QED Therapeutics at 1-844-550-BBIO (2246) or go to www.TRUSELTIQ.com.