

Questions and Answers about PEMAZYRE



Here is some useful information about PEMAZYRE. Remember, every case of cholangiocarcinoma (CCA) is unique, and your healthcare provider is your best source of information for CCA.

INDICATIONS AND USAGE

PEMAZYRE® is a prescription medicine that is 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 a certain type of abnormal FGFR2 gene and make sure that PEMAZYRE is right for you.

It is not known if PEMAZYRE is safe and effective in children. PEMAZYRE is approved based on tumor response and duration of response. There are ongoing studies to show whether PEMAZYRE can improve survival or symptoms.

How can next-generation sequencing (NGS) help me?

- NGS is a type of molecular profiling test that is performed on a sample of the tumor that can detect many different abnormal gene changes that may be present in CCA
- The information from NGS testing can help determine how your disease is treated. For this reason, it's important to talk to your healthcare provider about NGS testing as early as possible after your diagnosis

What happens if the NGS test shows I have FGFR2 fusions or rearrangements?

- FGFR2 fusions are a type of abnormal gene change that can cause CCA found in up to 16% of patients with intrahepatic CCA, making it one of the most common types of abnormal gene changes in this type of cancer
- If a molecular profiling test shows you have an FGFR2 fusion, you may be eligible to receive PEMAZYRE
- PEMAZYRE is a treatment option that may be considered for adults with CCA that has spread or cannot be removed by surgery who test positive for FGFR2 fusion who have already received a previous treatment

How does PEMAZYRE work?

- PEMAZYRE is not chemotherapy; it is a targeted treatment for cholangiocarcinoma
- FGFR2 fusions can cause your cells to make an abnormal version of the FGFR2 protein, which can lead to tumor growth in CCA
- PEMAZYRE helps stop the activity of the abnormal FGFR2 protein
- By doing this, PEMAZYRE may help reduce the size of the targeted tumor by a certain amount or cause it to disappear (this does not always mean the cancer has been cured)

How do I take PEMAZYRE?

- Take PEMAZYRE exactly as your healthcare provider tells you
- PEMAZYRE is taken on a 21-day cycle: you take one tablet a day for 14 days, followed by a 7-day period where you don't take any tablets
- Take PEMAZYRE once a day, at the same time each day
- Take PEMAZYRE with or without food

- Swallow tablets whole. Do not crush, chew, split, or dissolve PEMAZYRE tablets

- You should not eat or drink grapefruit products during treatment with PEMAZYRE
- Your healthcare provider may change your dose of PEMAZYRE, or may temporarily or completely stop treatment if you get certain side effects

How many patients have been treated with PEMAZYRE?

- PEMAZYRE was approved by the FDA in April of 2020. It has been available for over 2 years and has been used to treat more than 800 patients

What are the potential side effects of PEMAZYRE?

- PEMAZYRE may cause serious side effects, including eye problems, high phosphate levels in your blood (hyperphosphatemia) and a buildup of minerals in different tissues of your body
- The most common side effects include: hair loss, diarrhea, nails separate from the bed or poor formation of the nail, feeling tired, change in sense of taste, nausea, constipation, mouth sores, dry eyes, dry mouth, decrease in appetite, vomiting, joint pain, stomach-area (abdominal) pain, low phosphate in blood, back pain, and dry skin. **See Important Safety Information on the next page**

What should I do if I experience a side effect?

- Tell your healthcare provider right away if you experience a side effect, even if you are not sure it is related to treatment
- Your healthcare provider may need to stop or interrupt treatment
- Your healthcare provider may be able to offer ways to help manage side effects while you are taking PEMAZYRE

Are there any support or assistance programs available for patients taking PEMAZYRE?

- At **IncyteCARES for PEMAZYRE**, our team can help you understand your insurance coverage, explore financial assistance options, and provide ongoing support
- For more information, visit [IncyteCARES.com](https://www.incyte.com/cares)
- Call IncyteCARES for PEMAZYRE at **1-855-452-5234**, Monday through Friday, 8 AM-8 PM ET

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IMPORTANT SAFETY INFORMATION

Before you take PEMAZYRE, tell your healthcare provider about all of your medical conditions, including if you:

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

Females who can become pregnant:

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

Males with female partners who can become pregnant:

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

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of PEMAZYRE?

PEMAZYRE may cause serious side effects, including:

- **Eye problems.** Certain eye problems are common with PEMAZYRE but can also be serious. Eye problems include dry eye or inflamed eyes, inflamed cornea (front part of the eye), increased tears, and a disorder 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 PEMAZYRE, every 2 months for the first 6 months, and then every 3 months during treatment with PEMAZYRE.
 - You should use artificial tears or 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 during treatment with PEMAZYRE, including: blurred vision, flashes of light, or see black spots. You may need to see an eye specialist right away.
- **High phosphate levels in your blood (hyperphosphatemia) and buildup of minerals in different tissues in your body.** Hyperphosphatemia is common with PEMAZYRE 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 PEMAZYRE.

- Your healthcare provider may prescribe changes in your diet or phosphate lowering therapy, or change, interrupt, or stop PEMAZYRE if needed.
- Tell your healthcare provider right away if you develop any muscle cramps, or numbness or tingling around your mouth.

The most common side effects of PEMAZYRE for cholangiocarcinoma include:

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| • hair loss | • dry eyes |
| • diarrhea | • dry mouth |
| • nails separate from the bed or poor formation of the nail | • decrease in appetite |
| • feeling tired | • vomiting |
| • change in sense of taste | • joint pain |
| • nausea | • stomach-area (abdominal) pain |
| • constipation | • low phosphate in blood |
| • mouth sores | • back pain |
| | • dry skin |

These are not all the possible side effects of PEMAZYRE. 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. You may also report side effects to Incyte Medical Information at 1-855-463-3463.

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

General information about the safe and effective use of PEMAZYRE.

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

Please see the [Full Prescribing Information](#) for PEMAZYRE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

