



For the following indication, ^{Pr}PEMAZYRE[®] has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

PEMAZYRE[®] is used to treat adults with a type of cancer called cholangiocarcinoma (bile duct cancer) when it:

- has a type of abnormality in a specific gene called fibroblast growth factor receptor 2 (FGFR2); **and**
- has been treated previously
- cannot be removed with surgery
- is at an advanced stage or has spread to other parts of the body (called metastatic).

A test will be done to find out if the cancer has an FGFR2 gene abnormality. This is to make sure that PEMAZYRE[®] is right for you.

^{Pr}**Pemazyre[®]** 
pemigatinib tablets
13.5mg • 9mg • 4.5mg

GETTING STARTED
with PEMAZYRE[®]

Your treatment guide

Information you'll find in this booklet

What is cholangiocarcinoma (CCA)?	4
How does PEMAZYRE® work?	6
What is the usual dose of PEMAZYRE®?	8
How do I take PEMAZYRE®?	10
What kind of monitoring will be required during treatment?	12
What are the possible side effects of treatment?	14
Your PEMAZYRE® treatment tracker	17
Your personalized discussion guide	19
The Incyte Solutions™ Support Program	21
Tips for caregivers and loved ones	22
Frequently asked questions (FAQ)	24
Glossary	26

The next step in your journey with PEMAZYRE®

This booklet was designed to help you navigate through the treatment process with PEMAZYRE®. You can gain insight into how PEMAZYRE® works, how to take PEMAZYRE®, and more.

Your healthcare team contact information

Fill out the information below to help you stay in contact with your healthcare team.

Hospital (or clinic) name _____

Address _____

Email _____

Phone _____

Doctor's name _____

Email _____

Phone _____

Nurse's name _____

Email _____

Phone _____

Other contact(s) _____

Email _____

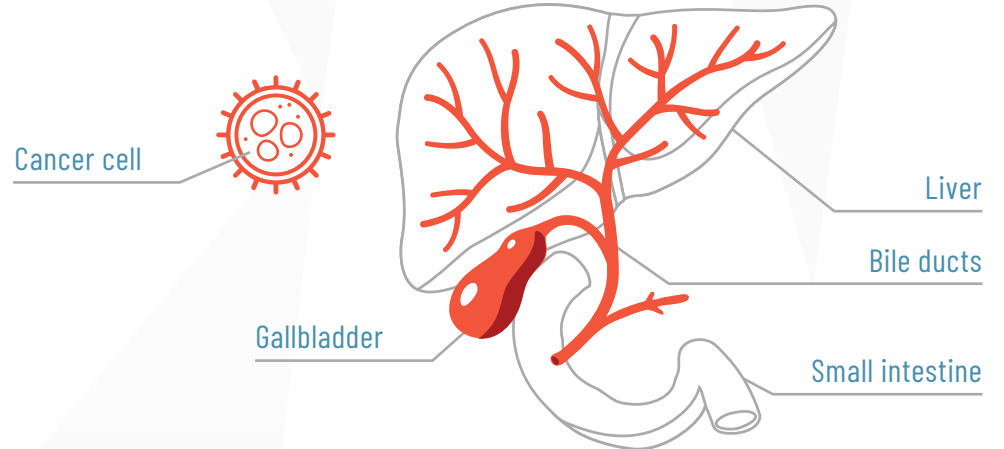
Phone _____



What is cholangiocarcinoma (CCA)?



CCA, also known as bile duct cancer, is a **rare disease** in which cancerous cells form in the bile ducts.

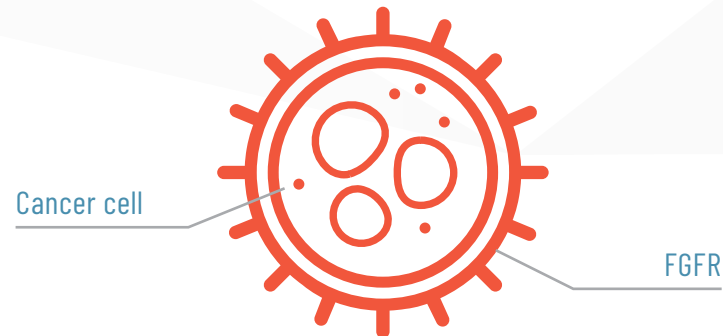


Some people with bile duct cancer have FGFRs that are **more active** than normal.

Understanding fibroblast growth factor receptors (FGFRs)

FGFR2: A specific kind of FGFR

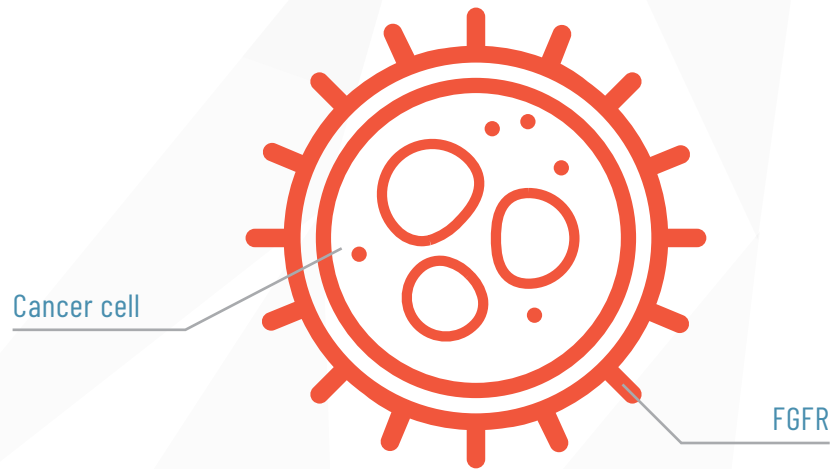
- FGFRs are proteins found on cells.
- These proteins help the cells grow and divide.



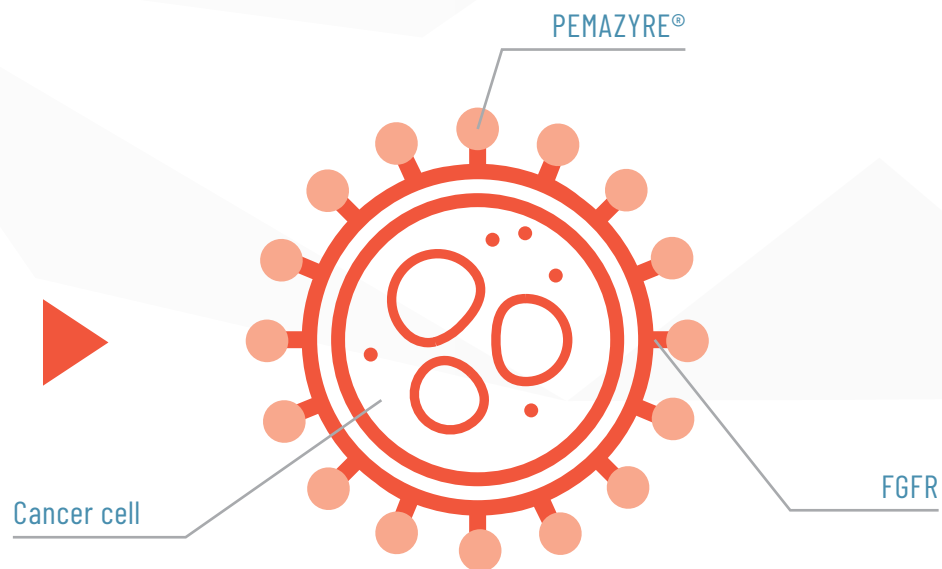
With testing, FGFR genetic abnormalities can be detected.

How does PEMAZYRE® work?

PEMAZYRE® works by blocking the activity of FGFRs



Some people with bile duct cancer have FGFRs that are more active than normal.



By blocking the activity of FGFRs, PEMAZYRE® should **slow down the growth and spread of bile duct cancer cells.**

What is the usual dose of PEMAZYRE®?



PEMAZYRE® is available in blister packs of **once-daily tablets**.

Usual dose of PEMAZYRE®

The typical PEMAZYRE® treatment cycle is 14 days (2 weeks) of treatment followed by 7 days (1 week) off treatment.



14 days



7 days



13.5 mg once-daily

Followed by



No treatment

21-day cycle (3 weeks)

PEMAZYRE® is also available in 9 mg and 4.5 mg tablets



You may receive a lower dose if you are taking certain medications or have severe kidney or liver problems. Your healthcare professional may change your dose of PEMAZYRE® or may temporarily or completely stop your treatment if you develop certain side effects, or your disease gets worse.

Storing PEMAZYRE®



Store PEMAZYRE® between **15°C to 30°C**.
Keep **out of sight and reach of children**.

How do I take PEMAZYRE®?



1. Take exactly as your healthcare professional tells you.

Check with your doctor or pharmacist if you are not sure.



2. Take one tablet with or without food, once per day, at about the same time each day.



3. Swallow tablets whole. Do not crush, chew, split or dissolve tablet.



4. Take your PEMAZYRE® every day for 14 days (2 weeks) in a row.

This is followed by 7 days (1 week) with no treatment (treatment-free week). Two weeks of treatment and one week with no treatment make up a 21-day cycle.

If you miss a dose



**If it has been 4 hours or more
(or if you vomit after taking your dose)**

Do NOT make up the dose. Skip it and continue with your next dose at the usual time. Do not take an extra dose the next day to make up for the missed dose.



If it has been less than 4 hours

Take PEMAZYRE® as soon as you remember and continue your next dose at the usual time.



During treatment with PEMAZYRE®, do not eat or drink grapefruit products or products that contain grapefruit extract. These can affect the way the medicine works.



Driving and using machines: Before you do tasks which may require special attention, wait until you know how you respond to PEMAZYRE®. If you experience vision problems, do not drive or use tools or machines until the side effect goes away.

What kind of monitoring will be required during treatment?

Treatment with PEMAZYRE® can cause serious side effects. You will have scheduled visits with your healthcare team so that they can monitor you and assess your response to treatment.



Potential side effect

Monitoring required

Hyperphosphatemia
(high phosphate levels in your blood)

OR

Hypophosphatemia
(low levels of phosphate in your blood)

Your healthcare team will do blood tests to check levels of phosphate in your blood.

These tests will be done **14 days after you start PEMAZYRE®**. They will be repeated about **every 6 weeks**.



Eye and vision problems
including dry eye, inflamed eyes, increased tears, and serous retinal detachment (which is when fluids build up in the eye and causes the retina to detach)

Your healthcare professional will check your eyes and vision **before you start taking PEMAZYRE®, every 2 months for the first 6 months of your treatment and then every 3 months thereafter**.

If you experience **hyperphosphatemia** or **hypophosphatemia**, your healthcare professional may:

- advise you to change the amount of phosphate in your diet,
- change your dose of PEMAZYRE®, or
- tell you to start or stop taking medications that affect the amount of phosphate in your blood.

Because of the risk for hyperphosphatemia, avoid using antacids that contain calcium and supplements that are phosphate-based.

Serous retinal detachment is a serious common side effect of taking PEMAZYRE®.

Tell your doctor if you develop any changes in your vision during your treatment with PEMAZYRE® such as:

- blurred vision,
- flashes of light,
- or seeing black spots.

You may need to see an eye specialist (an ophthalmologist) right away.

Your healthcare professional will check your eyes and vision before you start taking PEMAZYRE® and continually throughout your treatment.

Serious side effects

Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Hyperphosphatemia (high blood phosphate levels): muscle cramps and tingling		✓	
Hypophosphatemia (low blood phosphate levels): muscle weakness and pain, confusion, seizures, tea-coloured urine, heart or breathing problems		✓	
Nail or skin problems: nails separating from the bed; nail pain, breaking of the nails, infected skin around the nails; colour or texture changes, dry skin		✓	
Palmar-Plantar erythrodysesthesia (hand-foot syndrome): swelling, peeling or tenderness, mainly on the hands and feet		✓	
Arthralgia: joint pain		✓	
Urinary tract infection (infection of the urinary system): pain or burning sensation while urinating, frequent urination, blood in the urine		✓	
Dehydration: feeling thirsty, infrequent urination, feeling dizzy or tired, dark yellow urine, dry mouth and lips		✓	
Hypercalcemia (high blood calcium levels): increase in urine production, increase in thirst, nausea, weakness, confusion		✓	
Anemia (decreased number of red blood cells): fatigue, weakness, loss of energy, fast heart rate, pale complexion, shortness of breath		✓	
Hyponatremia (low blood sodium levels): nausea, vomiting, fatigue, headache, confusion, seizure		✓	

Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Vision problems including serous retinal detachment (when fluid builds up under the retina): blurred vision, black spots, flashes of light, inflammation of the cornea, dry eye		✓	
Trichiasis: eyelashes grow inward to the eye		✓	
Kidney problems: passing low amounts of urine, nausea, swelling in legs and ankles, confusion, difficulty breathing		✓	
Cholangitis (infection of the biliary tract): abdominal pain, fever, chills, jaundice (yellowing of the skin or whites of the eyes), nausea, vomiting		✓	
Pleural effusion (a buildup of fluid between the tissues that line the lungs)		✓	
Failure to thrive (a decline in adults, often associated with physical frailty, functional disability, and/or neuropsychiatric impairment): weight loss, weakness, decreased physical activity, difficulty in performing selfcare, change in mental status		✓	
Sepsis (a serious condition caused by infection and the body's response to infection potentially leading to organ dysfunction): low blood pressure, fast heart rate, fever, decrease in urination, difficulty breathing, altered mental status		✓	
Intestinal obstruction (an interruption to the flow of the intestines): abdominal pain or distention, nausea, vomiting		✓	
Bile duct obstruction (blockage of the bile duct that transports bile from the liver to the gallbladder and small intestine): abdominal pain, dark urine, fever, itching, jaundice (yellowing of the skin or whites of the eyes), nausea, vomiting, pale coloured stools		✓	

What are the possible side effects of treatment?

These are not all the possible side effects you may feel when taking PEMAZYRE®. If you experience any side effects not listed here, contact your healthcare professional.

- Hair loss
- Abnormal hair growth
- Feeling tired
- Dizziness
- Taste changes
- Heartburn or indigestion
- Dry mouth
- Mouth sores
- Nausea
- Vomiting
- Constipation
- Headache
- Nose bleeds
- Fever
- Decreased appetite
- Diarrhea
- Abdominal pain
- Back pain
- Pain in the arms or legs
- Muscle pain and stiffness
- Swelling of the arms and legs
- Weight decreased

Contact your healthcare professional if you need information about how to manage your side effects.



PEMAZYRE® can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment and will interpret the results.



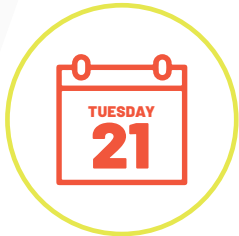
If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Your PEMAZYRE® treatment tracker

Throughout treatment, it's important to remember when to take your PEMAZYRE® tablet and keep track of your appointments. To help you with this, work with your healthcare team and consider the following tips:



Set a **daily reminder** on your phone, watch, or other device



Enter the dates of your future appointments into a **calendar**, such as on your phone or online



Use the **personalized discussion guide** on page 19 to write down anything you wish to discuss with your doctor

Tracking your treatment each cycle

With the help of your healthcare team, fill in this calendar to help you track your one cycle of treatment, which is 21 days (14 days on treatment followed by 7 days off). Consider writing down the dates and location of any doctors' appointments, such as follow-ups or visits to the ophthalmologist. You can even check off each day once you've taken your medication.

S	M	T	W	T	F	S
Date: _____	Date: _____	Date: _____	Date: _____	Date: _____	Date: _____	Date: _____

Notes

Your personalized discussion guide

Preparing for your PEMAZYRE® treatments

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PEMAZYRE®. Talk about any health conditions or problems you may have, including if you:

- have problems swallowing tablets
- have severe liver problems
- have severe kidney problems

Pregnancy and breastfeeding: Talk to your doctor if you are pregnant, breastfeeding, able to get pregnant, or having sex with someone who can get pregnant. You should not be pregnant while you are taking PEMAZYRE®. It may harm your unborn baby or make you lose the pregnancy. Use effective birth control during treatment with PEMAZYRE® and for 1 month after your last dose.



Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Keeping track of how you feel during treatment

Throughout treatment, keep track of how you're feeling. This can help you and your healthcare team monitor how you're doing and guide discussions about how to manage or answer any questions you may have.

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Use this space to write down anything else you might want to discuss with your healthcare team at your next appointment, such as any medications you currently take or questions you may have.



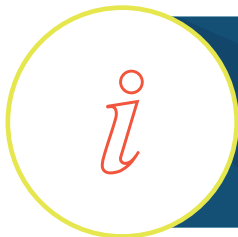
Refer to page 24 for frequently asked questions you may wish to discuss with your doctor.

The Incyte Solutions™ Support Program

At Incyte Biosciences Canada, we want to help provide support for patients to help them throughout treatment. That is why Incyte Solutions™ is available to provide resources for patients who have been prescribed PEMAZYRE®.

You may be eligible for a number of support services, such as:

- Specialized pharmacies and home delivery program
- Assistance in communicating with your drug plan and/or insurance company to help secure reimbursement coverage
- Financial assistance



Discover the support services Incyte Solutions™ has to offer.
Call **1-84-INCYTE-00** (1-844-629-8300) or send an email to **support@incytesolutions.ca**.



Tips for caregivers and loved ones

Things to keep in mind as a caregiver

- Be open and **honest** with each other. It is important to remember that you're both on the same team and want the best outcome.
- It's good to be **encouraging**, but it's also important not to tell your loved one to "always stay positive." They may think that you're trying to discount their legitimate fears, concerns or sad feelings.
- **Respect** your loved one's privacy. Don't disclose information about their diagnosis and treatment without their consent. Try to be understanding if they don't want to share all the details about what they're going through.

Ways to help your loved one during their PEMAZYRE® treatment



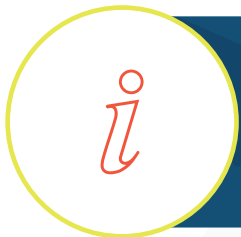
Use a calendar to track your loved one's PEMAZYRE® treatment schedule



Offer to arrange transport to help your loved one get to doctors' appointments



Remind your loved one to pair taking their PEMAZYRE® tablet with their other daily routines (e.g., brushing their teeth and mealtimes)



Refer to page 14 for the common serious side effects associated with taking PEMAZYRE®. Knowing these symptoms can help you and your loved one know when to contact their healthcare professional.

Tips to help you communicate with your loved one's healthcare team

- Write down any questions you may have. Let the doctor know you have a list so that they can set time aside to answer your questions.
- Take notes. Write down any important information that you or your loved one needs to remember.
- Ask for written information about your loved one's diagnosis and treatment plan.
- Ask about the common side effects patients experience.
- Encourage your loved one to share any symptoms or side effects with their doctor.



As a caregiver it is important to remember to take care of yourself.

- **Make time for yourself** by incorporating things you enjoy into your daily schedule. This can include getting some form of exercise, calling your friends, or even keeping up with a hobby.
- **Ask for help** from a family member, friend, or healthcare professional if you're unable to do a task for your loved one. Keep a list of your caregiving tasks so you know where others can help.
- **Be honest with yourself** when you need a break as a caregiver. Take at least 30 minutes a day to yourself for stress relieving activities.



For more information and to discover caregiver support services, check out the Canadian Cancer Society at **www.cancer.ca**.

Frequently asked questions (FAQ)

Does it matter what time I take my PEMAZYRE® tablet?

You should take PEMAZYRE® tablet with or without food, once per day. It does not matter what time of day you choose to take your PEMAZYRE® tablet, but it should be taken at the same time each day.

Why was my dose of PEMAZYRE® changed?

You may have received a lower dose if you are taking certain medications or have severe kidney or liver problems. Your healthcare professional may also change your dose of PEMAZYRE® or may temporarily or completely stop your treatment if you develop certain side effects, or your disease gets worse.

When should I stop taking PEMAZYRE®?

Take PEMAZYRE® exactly as your healthcare professional tells you and for as long as you are told to do so. Check with your doctor or pharmacist if you are not sure.

I have started to notice changes in my vision such as blurred vision, flashes of light and black spots. When should I contact my doctor?

Contact your healthcare professional right away if you experience any changes in vision during your treatment with PEMAZYRE®.

How will I track my appointments?

Refer to page 17 for your PEMAZYRE® treatment tracker to help you stay on top of your appointments and other aspects of treatment.

Where can I turn to for support?

Incyte Solutions™ is available to help support you throughout the treatment process. To learn more about your condition and to access additional support resources, check out the following websites:



www.cholangiocarcinoma.org



**Canadian
Cancer
Society**

www.cancer.ca

CANADIAN
LIVER
FOUNDATION



FONDATION
CANADIENNE
DU FOIE

www.liver.ca



Canadian Organization
for Rare Disorders

www.raredisorders.ca



If you have any additional questions, write them down and discuss them with your healthcare team at your next appointment. You can also call **1-833-309-2759** or email **medinfocanada@incyte.com**.

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Glossary

Bile

A fluid made by the liver and stored in the gallbladder. Bile is excreted into the small intestine, where it helps digest fat.

Bile duct

A tube through which bile passes in and out of the liver.

Cholangiocarcinoma (CCA)

A rare disease in which cancerous cells form in the bile ducts (also known as bile duct cancer).

Fibroblast growth factor receptors (FGFRs)

Proteins found on cells. These proteins help the cells grow and divide.

Ophthalmologist

A doctor who treats eye diseases.

Notes

Notes regarding PEMAZYRE® treatment

Notes

