Pr Pemazyre®
pemigatinib tablets
13.5 mg • 9 mg • 4.5 mg

PrPEMAZYRE® has been issued conditional marketing authorization pending the results of studies to verify its clinical benefit. Patients should be advised of this conditional marketing authorization.

# STARTING PATIENTS ON **PEMAZYRE®**[1]


PEMAZYRE® (pemigatinib) is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement.

**Before initiating treatment:**

- Confirm the presence of an FGFR2 fusion or rearrangement using a validated test
- Perform ophthalmological exams including:
  - Visual acuity test
  - Slit-lamp examination
  - Fundoscopy
  - Optical coherence tomography

  Repeat these ophthalmological exams every 2 months for the first 6 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms.
- Verify the pregnancy status of female patients

**Recommended dosage** is 13.5 mg orally once a day for 14 consecutive days, followed by 7 days off therapy, in 21-day cycles. Continue treatment until disease progression or unacceptable toxicity. Tablets may be taken with or without food and should not be taken with grapefruit, its juice, or grapefruit extract. The dose strength may be reduced depending on side effects.

- **First dose reduction:** 9 mg taken orally once daily, 14 days on, 7 days off therapy
- **Second dose reduction:** 4.5 mg taken orally once daily, 14 days on, 7 days off therapy
- **If unable to tolerate 4.5 mg once daily:** permanently discontinue PEMAZYRE®

**Dosage modifications in special populations:**

**Renal impairment:** for patients with severe renal impairment (GFR <30 mL/min), the starting dose should be reduced to 9 mg. No dosage modification is required for patients with end-stage renal disease on dialysis. No dose modification is recommended for patients with mild to moderate renal impairment (GFR ≥30 to <90 mL/min).

**Hepatic impairment:** for patients with severe hepatic impairment (total bilirubin >3 × ULN with any AST), the starting dose should be reduced to 9 mg. No dose modification is recommended for patients with mild (total bilirubin >ULN to 1.5 × ULN or AST >ULN) or moderate (total bilirubin >1.5–3 × ULN with any AST) hepatic impairment.

**Please refer to the Product Monograph for more information on the recommended dose and dose adjustments. A link to the Product Monograph can be found on the next page or at www.IncyteOnco.ca – a resource hub with resources for healthcare professionals.**

**Notes**

FGFR2: fibroblast growth factor receptor 2; GFR: glomerular filtration rate; ULN: upper limit of normal; AST: aspartate aminotransferase.

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### Dosage modifications in case of co-administration of PEMAZYRE® with CYP3A4 inhibitors and CYP3A inducers:[1]

- Avoid co-administration with moderate or strong CYP3A4 inhibitors (e.g., erythromycin, clarithromycin). If co-administration cannot be avoided, reduce the PEMAZYRE® dosage as per recommendations on the previous page.
- Avoid co-administration with strong or moderate CYP3A inducers (e.g., rifampin, efavirenz).

**Risk management for hyperphosphatemia:**[1,2] Phosphate levels should be assessed 14 days after treatment initiation and monitored every 2 cycles (approximately 6 weeks) thereafter.

For elevated phosphate concentrations (shown below), follow dose modification guidelines in the Product Monograph.

- >5.5 mg/dL (2.3 mmol/L)
- >7 mg/dL (2.3 mmol/L) to ≤10 mg/dL (3.2 mmol/L)
- >10 mg/dL (3.2 mmol/L)

Start all patients on a low phosphate diet when their phosphate level is >5.5 mg/dL and consider adding a phosphate lowering therapy when a patient's level is >7 mg/dL. Consider discontinuing phosphate lowering therapy during PEMAZYRE® treatment breaks or if the phosphate level falls below normal.

For additional information related to pemigatinib, consider the following resources:

- Contact your **Incyte representative**
- Review the clinical practice resource on FGFR inhibitor therapy in patients with advanced cholangiocarcinoma (available online) from the **Canadian Association of Nurses in Oncology***
- Visit **www.IncyteOnco.ca** for additional PEMAZYRE® resources, including patient education materials, efficacy data, guidance on managing adverse events, and more

Consider providing your patient information on the following patient support organizations:

- **Cholangiocarcinoma Foundation®** – www.cholangiocarcinoma.org
- **Canadian Cholangiocarcinoma Collaborative (C3)** – www.cholangio.ca
- **Cholangio-Hepatocellular Carcinoma Canada** – www.mychcc.ca

**Clinical use:**

Clinical effectiveness of PEMAZYRE® is based on ORR and DoR from a single-arm Phase 2 trial in patients with specific FGFR2 rearrangements.

Treatment with PEMAZYRE® should be initiated following confirmation of a FGFR2 fusion or rearrangement using a validated test.

Pediatrics (18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

**Contraindications:**

- PEMAZYRE® is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

**Relevant warnings and precautions:**

- If patients experience symptoms affecting their vision, it is recommended that they do not drive or use machines until the effect subsides.
- Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis may be associated with hyperphosphatemia and has been observed with PEMAZYRE® treatment.
- Hypophosphatemia has been observed with PEMAZYRE®.
- Phosphate concentrations should be assessed 14 days after initiating PEMAZYRE® treatment and then monitored every 6 weeks thereafter.
- Opthalmological exams including the visual acuity test, slit-lamp exam, fundoscopy, and optical coherence tomography should be performed prior to initating treatment with PEMAZYRE® and throughout treatment.
- Pemigatinib may increase serum creatinine due to a blockade of tubular secretion via renal transporters OCT2 and MATE1.
- PEMAZYRE® can cause serous retinal detachment events, which may present with symptoms such as blurred vision, visual floaters, or photopsia.
- PEMAZYRE® may cause fetal harm and potential loss of pregnancy. Advise females of reproductive potential to use effective contraception during treatment with PEMAZYRE® and for 1 month after the last dose.
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE® and for 1 month after the last dose.
- Advise women not to breastfeed during treatment with PEMAZYRE® and for 1 month after the final dose.

**For more information:**

Please consult the Product Monograph at pdf.hres.ca/dpd_pm/00062968.PDF for important information relating to monitoring and laboratory tests, adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-833-309-2759 or contacting medinfocanada@incyte.com.

* Infigratinib is not currently available in Canada.
ORR: overall response rate; DoR: duration of response; FGFR2: fibroblast growth factor receptor 2.

**References: 1.** PEMAZYRE® Product Monograph. Incyte Corporation. September 8, 2021. **2.** Canadian Association of Nurses in Oncology (CANO). Clinical practice resource: FGFR inhibitor therapy (pemigatinib and infigratinib) in patients with advanced cholangiocarcinoma. Version 10.2022.