Pemazyre®
(pemigatinib) tablets
13.5mg • 9mg • 4.5mg

Managing Adverse Reactions With PEMAZYRE

A Pocket Guide for How to Manage Select Adverse Reactions

3+ YEARS

OF **CLINICAL EXPERIENCE** SINCE FDA APPROVAL WITH **1,000+ PATIENTS** TREATED[1]*

*Commercially available in the US since 2020.

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Pemazyre® (pemigatinib) tablets 13.5 mg · 9 mg · 4.5 mg

PEMAZYRE is the first FDA-approved treatment for adult patients with previously treated, unresectable locally advanced or metastatic CCA with an *FGFR2* fusion or other rearrangement as detected by an FDA-approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

WARNINGS AND PRECAUTIONS

PEMAZYRE can cause ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity.

These are not all of the risks. Important Safety Information is presented in this pocket guide.

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

To report **SUSPECTED ADVERSE REACTIONS**, contact Incyte Corporation at 1-855-463-3463 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Recommended Dosage and Schedule for PEMAZYRE® (pemigatinib)[2]

How is PEMAZYRE given?

14 consecutive days of once-daily therapy | 2 WEEKS

7 days of no therapy | 1 WEEK

The recommended dosage of PEMAZYRE is **13.5 mg** taken orally once daily on a 21-day treatment cycle.

- PEMAZYRE can be taken with or without food
- Instruct patients to take their dose of PEMAZYRE at approximately the same time every day
- Do not crush, chew, split, or dissolve tablets
- If the patient misses a dose of PEMAZYRE by 4 or more hours, or if vomiting occurs, they should resume dosing with the next scheduled dose

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Dosage Modifications of PEMAZYRE® (pemigatinib) for Adverse Reactions[2]

Dosage reductions should be considered for the management of toxicities or tolerability

All doses are taken **once daily for 14 days** followed by 7 days off therapy in 21-day cycles

Please see the full Prescribing Information and follow the dosage modification guidelines.

Permanently discontinue PEMAZYRE if patient is unable to tolerate 4.5 mg once daily for 14 days of each 21-day cycle.

One pill once daily that can be taken at home with or without food regardless of dose

FIGHT-202: A Multicenter, Open-Label, Single-Arm Study of PEMAZYRE

FIGHT-202 (NCT02924376) Study Design Overview[2,3]

- Phase 2 single-arm study of PEMAZYRE in adults (N=107) with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor 2 (FGFR2) fusion or other rearrangement
- Patients received PEMAZYRE in 21-day cycles at a starting dosage of 13.5 mg orally once daily for 14 days, followed by 7 days off therapy

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Adverse Reactions (≥15%) in Patients Receiving PEMAZYRE® (pemigatinib) in FIGHT-202 (N=146)[2]

ADVERSE REACTION	ALL GRADES, %[a]	GRADES 3 or 4, %[b]
Metabolism and nutrition disorders		
Hyperphosphatemia[c]	60	0
Decreased appetite	33	1.4
Hypophosphatemia[d]	23	12
Dehydration	15	3.4
Skin and subcutaneous tissue disorders		
Alopecia	49	0
Nail toxicity[e]	43	2.1
Dry skin	20	0.7
Palmar-plantar erythrodysesthesia syndrome	15	4.1

[a]Graded per NCI CTCAE v4.03.

[b]Only Grades 3 to 4 were identified.

[c]Includes hyperphosphatemia and blood phosphorous increased; graded based on clinical severity and medical interventions taken according to the "investigations-other, specify" category in NCI CTCAE v4.03.

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received PEMAZYRE.

Adverse Reactions (≥15%) in Patients Receiving PEMAZYRE® (pemigatinib) in FIGHT-202 (N=146)[2]

ADVERSE REACTION	ALL GRADES, %[a]	GRADES 3 or 4, %[b]
Metabolism and nutrition disorders		
Hyperphosphatemia[c]	60	0
Decreased appetite	33	1.4
Hypophosphatemia[d]	23	12
Dehydration	15	3.4
Skin and subcutaneous tissue disorders		
Alopecia	49	0
Nail toxicity[e]	43	2.1
Dry skin	20	0.7
Palmar-plantar erythrodysesthesia syndrome	15	4.1
Gastrointestinal disorders		
Diarrhea	47	2.7
Nausea	40	2.1
Constipation	35	0.7
Stomatitis	35	5
Dry mouth	34	0
Vomiting	27	1.4
Abdominal pain	23	4.8
General disorders		
Fatigue	42	4.8
Edema peripheral	18	0.7
Nervous system disorders		
Dysgeusia	40	0
Headache	16	0
Eye disorders		
Dry eye[f]	35	0.7
Musculoskeletal and connective tissue disorders		
Arthralgia	25	6
Back pain	20	2.7
Pain in extremity	19	2.1
Infections and infestations		
Urinary tract infection	16	2.7
Investigations		
Weight loss	16	2.1

[a]Graded per NCI CTCAE v4.03.

[b]Only Grades 3 to 4 were identified.

[c]Includes hyperphosphatemia and blood phosphorous increased; graded based on clinical severity and medical interventions taken according to the "investigations-other, specify" category in NCI CTCAE v4.03.

[d]Includes hypophosphatemia and blood phosphorous decreased.

[e]Includes nail toxicity, nail disorder, nail discoloration, nail dystrophy, nail hypertrophy, nail ridging, nail infection, onychalgia, onychoclasis, onycholysis, onychomadesis, onychomycosis, and paronychia.

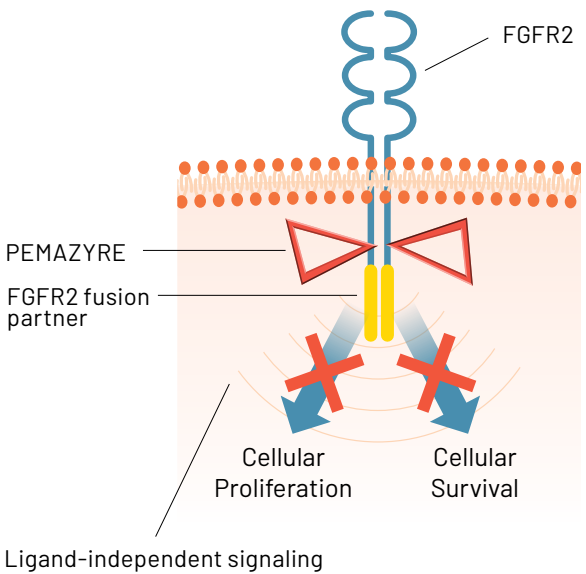
[f]Includes dry eye, keratitis, lacrimation increased, pinguecula, and punctate keratitis.

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Clinically relevant adverse reactions occurring in ≤10% of patients included fractures (2.1%). In all patients treated with pemigatinib, 0.5% experienced pathologic fractures (which included patients with and without cholangiocarcinoma [N=635]). Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis associated with hyperphosphatemia were observed with PEMAZYRE treatment.[2]

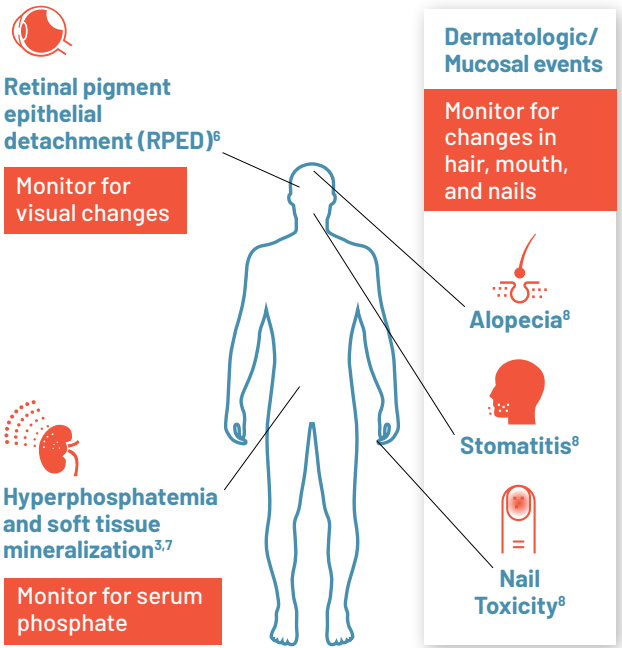
PEMAZYRE® (pemigatinib) Targets and Inhibits FGFR1, 2, and 3

PEMAZYRE Mechanism of Action[2,4]



FGFR2 fusions in cholangiocarcinoma can be detected by use of NGS.[5]

FGFR-Inhibition–Related Adverse Reactions of Interest[2]



Please see individual tabs for details on monitoring/management.

FGFR INHIBITION RELATED EFFECT

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

FGFR-Inhibition–Related Adverse Reactions of Interest[2] *(continued)*

PEMAZYRE® (pemigatinib) inhibits FGFR2 kinase activity, which may decrease tumor cell proliferation and survival in FGFR-driven tumors.[2]

Inhibition of FGFR may produce related adverse reactions including the following[3]:

- Retinal pigment epithelial detachment (RPED)
- Hyperphosphatemia and soft tissue mineralization
- Dermatologic/Mucosal events including nail toxicities, stomatitis, and alopecia

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Please see the following tabs for detailed information about monitoring for and managing these adverse reactions.

Recommended Dosage Modifications of PEMAZYRE for Adverse Reactions[2]

Please see dose modifications for RPED and Hyperphosphatemia in the respective tabbed sections that follow.

For Other Adverse Reactions

Grade 3 Adverse Reactions[a]	**Grade 4** Adverse Reactions[a]
Withhold PEMAZYRE until resolves to Grade 1 or baseline	**Permanently discontinue PEMAZYRE**
Resume PEMAZYRE at next lower dose if resolves within 2 weeks	
Permanently discontinue PEMAZYRE if does not resolve within 2 weeks **OR** for recurrent Grade 3 after 2 dose reductions	

[a]Severity as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Monitoring for RPED in Patients Taking PEMAZYRE® (pemigatinib)[2]

PEMAZYRE can cause RPED, which may cause symptoms such as blurred vision, visual floaters, or photopsia

Advise patients to inform you of any vision changes while taking PEMAZYRE

Perform comprehensive ophthalmological examinations, including optical coherence tomography (OCT)

OCT is a non-invasive imaging test that uses light waves to map and measure the thickness of distinctive layers of the retina.[9]

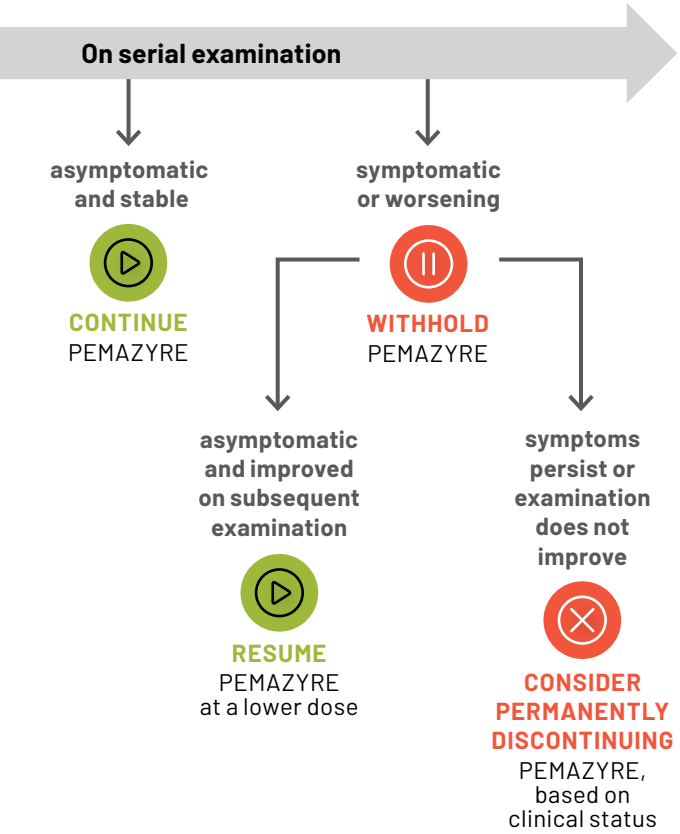
Prior to initiation of therapy › **Every 2 months** for the first 6 months of treatment › **Every 3 months** thereafter during treatment

For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of PEMAZYRE.[2]

Modify the dose or permanently discontinue PEMAZYRE as recommended on next panel.[2]

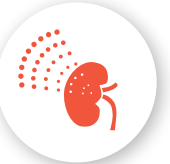
Advise patients that they should use artificial tear or substitutes, hydrating or lubricating eye gels as needed, in order to prevent or treat dry eyes.

Recommended Dose Modification of PEMAZYRE® (pemigatinib) for RPED[2]



Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Monitoring for Hyperphosphatemia in Patients Taking PEMAZYRE® (pemigatinib)



PEMAZYRE can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis.[2]

Monitor for Hyperphosphatemia

In the FIGHT-202 study, serum phosphate was measured on Day 1 of every cycle following a 1-week dosing holiday, starting with the second cycle of treatment with PEMAZYRE.[1]

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

See dose modifications on next page.

In the FIGHT-202 study, no patients discontinued treatment due to hyperphosphatemia.[1]

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

PEMAZYRE® (pemigatinib) Recommended Dosage Modification: Hyperphosphatemia[2]

Serum phosphate **>5.5 mg/dL**	**Initiate a low-phosphate diet**		
Serum phosphate **>7 to ≤10 mg/dL**	**Initiate phosphate lowering therapy** **Monitor** serum phosphate weekly	**Withhold PEMAZYRE** if levels are not <7 mg/dL within 2 weeks of starting phosphate-lowering therapy	**Resume PEMAZYRE** at the same dose when phosphate levels are <7 mg/dL for first occurrence
For subsequent recurrences, resume at a lower dose			
Serum phosphate **>10 mg/dL**	**Initiate phosphate lowering therapy** **Monitor** serum phosphate weekly	**Withhold PEMAZYRE** if levels are not ≤10 mg/dL within 1 week after starting phosphate-lowering therapy	**Resume PEMAZYRE at the next lower dose level** when phosphate levels are <7 mg/dL
If there is recurrence of serum phosphate >10 mg/dL following 2 dose reductions, **Permanently discontinue PEMAZYRE**			

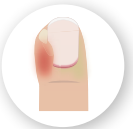
Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Nail Toxicities in Patients Taking PEMAZYRE® (pemigatinib)

Examples of nail toxicity in the FIGHT-202 study included[2]:

The illustrations included here represent examples of nail toxicities patients may experience. Patients should report any nail changes to their healthcare professional even if they don't match these images.



Paronychia
Infection of the tissue folds around a nail[10]

Onychauxis
Abnormal hypertrophy (thickening) of the nails[11]

Onychomadesis
Separation of nail plate from matrix due to cessation of growth[12]

Onycholysis
Painless separation of the nail from the nail bed[13]

Nail dystrophy
Malformation of the nail[14]

Nail discoloration
Abnormal change in the color of the nail

Nail Toxicity: Potential Management Approaches

Consider counseling and education on the potential for nail changes before initiation of treatment[8]

Preventative strategies may include avoidance of:

- Prolonged contact with water
- Repeated trauma
- Friction
- Pressure on the nails and nail beds

Patients may be advised to:

- Limit the use of nail polish removers or hardeners
- Avoid biting nails or cutting nails too short
- Use topical emollients
- Wear loose-fitting socks and footwear

Preventative correction of nail curvature may be considered.

Stomatitis: Potential Management Approaches

Consider counseling and education on the potential for stomatitis before initiation of treatment[8]

Preventative strategies may include[8]:

- Dental work to address tooth and gum disease before start of treatment
- Education regarding the importance of thorough and frequent cleaning of the oral cavity

Patients may be advised to[8]:

- Avoid salty, spicy, or citrus-based foods
- Avoid hot beverages

Potential management approaches may include[15]:

- Use of coating agents, such as bismuth salicylate, sucralfate, or other antacids
- Water-soluble mouth/lip lubricants
- "Magic mouthwash" (may include antifungals, antibacterials, steroids, and/or local anesthetics)
- Topical analgesics or oral analgesics
- Topical anesthetics

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Alopecia: Potential Management Approaches[8]

- Preventative measures normally considered for patients undergoing traditional chemotherapy (eg, scalp compression, scalp cooling, medications) may not be applicable

Management approaches to consider may include:

- Prophylactic or reactive topical medications for the scalp to encourage hair regrowth
- Topical high potency corticosteroid
- Camouflaging methods which create the appearance of naturally fuller hair

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Attention should be focused on early identification and management.

Counseling Patients on PEMAZYRE® (pemigatinib) About Adverse Events

- Please refer patients to the Patient Information section of the Full Prescribing Information for additional information on side effects of PEMAZYRE
- Advise patients that the dose of PEMAZYRE may be reduced/interrupted or the drug discontinued because of adverse reactions[2]
- A Treatment Tracker for patients to track their doses of PEMAZYRE is available at **pemazyre.com/pdf/DosingTracker.pdf** or through this QR code

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

For Adverse Reactions Covered in This Pocket Guide[2]

Ocular Toxicity

- Advise patients that they will need to see an eye specialist for a complete eye exam, including a study called optical coherence tomography (OCT), before beginning PEMAZYRE® (pemigatinib), every 2 months for the first 6 months, and then every 3 months during treatment
- Advise patients to inform you of any vision changes while taking PEMAZYRE, including blurred vision, flashes of light, or see black spots
- Advise patients with visual symptoms that they will be referred for ophthalmological evaluation urgently with follow-up every 3 weeks until resolution of symptoms or discontinuation of PEMAZYRE
- Also advise patients that they should use artificial tear or substitutes, hydrating or lubricating eye gels as needed, in order to prevent or treat dry eyes

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Hyperphosphatemia and Soft Tissue Mineralization

- Inform patients that PEMAZYRE may increase serum phosphate, that their serum phosphate will be monitored, and that they may be prescribed changes in their diet or given phosphate-lowering agents ("phosphate binders") if they develop hyperphosphatemia
- Advise patients to immediately inform you of any symptoms related to acute change in phosphate levels such as muscle cramps, numbness, or tingling around the mouth

Dermatologic/Mucosal Adverse Reactions

- See this guide for potential management approaches

Embryo-Fetal Toxicity

- Counsel patients as appropriate about the need for effective contraception

Warnings and Precautions: Embryo-Fetal Toxicity[2]

Based on findings in an animal study and its mechanism of action, PEMAZYRE® (pemigatinib) can cause fetal harm when administered to a pregnant woman.

Advise patients of potential risks

Pregnant women	Advise pregnant women of the potential risk to the fetus.
Female patients	Advise female patients of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the last dose. Advise females to inform their healthcare provider if they are pregnant or become pregnant. Inform female patients of the risk to a fetus and potential loss of pregnancy. Advise patients not to breastfeed during treatment with PEMAZYRE and for 1 week after the last dose.
Male patients	Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the last dose.

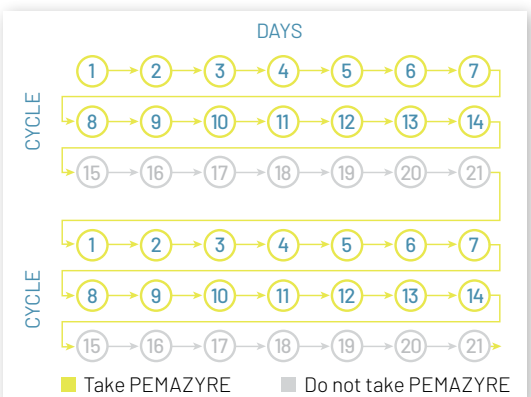
Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

Patient Treatment Tracker

Help provide a tool for your patients to track their doses of PEMAZYRE with a downloadable resource.

Visit **pemazyre.com/pdf/DosingTracker.pdf** or scan this QR code

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



IncyteCARES | Pemazyre (pemigatinib) tablets 13.5mg-9mg-4.5mg

IncyteCARES for PEMAZYRE

We're Here to Support Your Eligible Patients During Treatment

Our mission is to help your patients start and stay on therapy by assisting with access and ongoing support.

Information and resources available through IncyteCARES includes:

- Benefits verification and as-needed prior authorization or appeal support
- Pharmacy outreach call to help patients get started on treatment
- Flexibly scheduled calls from a pharmacy care team specialist
- Treatment history and medication monitoring
- Text message refill reminders
- Education and support resources
- Information about financial assistance options
- Practice resources and forms

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1-866-708-8806

Monday through Friday, 8 AM-8 PM ET

Visit
https://hcp.pemazyre.com/access-support
or scan this QR code

For more information about PEMAZYRE, visit hcp.PEMAZYRE.com.

Pemazyre® (pemigatinib) tablets 13.5 mg · 9 mg · 4.5 mg

IMPORTANT SAFETY INFORMATION

Ocular Toxicity

Retinal Pigment Epithelial Detachment (RPED): PEMAZYRE can cause RPED, which may cause symptoms such as blurred vision, visual floaters, or photopsia. Clinical trials of PEMAZYRE did not conduct routine monitoring including optical coherence tomography (OCT) to detect asymptomatic RPED; therefore, the incidence of asymptomatic RPED with PEMAZYRE is unknown.

Among 635 patients who received a starting dose of PEMAZYRE 13.5 mg across clinical trials, RPED occurred in 11% of patients, including Grade 3-4 RPED in 1.3%. The median time to first onset of RPED was 56 days. RPED led to dose interruption of PEMAZYRE in 3.1% of patients, and dose reduction and permanent discontinuation in 1.3% and in 0.2% of patients, respectively. RPED resolved or improved to Grade 1 levels in 76% of patients who required dosage modification of PEMAZYRE for RPED.

Perform a comprehensive ophthalmological examination including OCT prior to initiation of PEMAZYRE and every 2 months for the first

6 months and every 3 months thereafter during treatment. For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of PEMAZYRE. Modify the dose or permanently discontinue PEMAZYRE as recommended in the prescribing information for PEMAZYRE.

Dry Eye: Among 635 patients who received a starting dose of PEMAZYRE 13.5 mg across clinical trials, dry eye occurred in 31% of patients, including Grade 3-4 in 1.6% of patients. Treat patients with ocular demulcents as needed.

Hyperphosphatemia and Soft Tissue Mineralization

PEMAZYRE can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis. Increases in phosphate levels are a pharmacodynamic effect of PEMAZYRE. Among 635 patients who received a starting dose of PEMAZYRE 13.5 mg across clinical trials, hyperphosphatemia was reported in 93% of patients based on laboratory values above the upper limit of normal. The median time to onset of hyperphosphatemia was 8 days (range 1-169). Phosphate lowering therapy was required in 33% of patients receiving PEMAZYRE.

Monitor for hyperphosphatemia and initiate a low phosphate diet when serum phosphate level is >5.5 mg/dL. For serum phosphate levels >7 mg/dL, initiate phosphate lowering therapy and withhold, reduce the dose, or permanently discontinue PEMAZYRE based on duration and severity of hyperphosphatemia as recommended in the prescribing information.

Embryo-Fetal Toxicity

Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg.

Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during

treatment with PEMAZYRE and for 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the last dose.

Adverse Reactions: Cholangiocarcinoma

Serious adverse reactions occurred in 45% of patients receiving PEMAZYRE (n=146). Serious adverse reactions in ≥2% of patients who received PEMAZYRE included abdominal pain, pyrexia, cholangitis, pleural effusion, acute kidney injury, cholangitis infective, failure to thrive, hypercalcemia, hyponatremia, small intestinal obstruction, and urinary tract infection. Fatal adverse reactions occurred in 4.1% of patients, including failure to thrive, bile duct obstruction, cholangitis, sepsis, and pleural effusion.

Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received PEMAZYRE. Adverse reactions requiring permanent discontinuation in ≥1% of patients included intestinal obstruction and acute kidney injury.

Dosage interruptions due to an adverse reaction occurred in 43% of patients who received PEMAZYRE. Adverse reactions requiring dosage interruption in ≥1% of patients included stomatitis, palmar-plantar erythrodysesthesia syndrome, arthralgia, fatigue, abdominal pain, AST increased, asthenia, pyrexia, ALT increased, cholangitis, small intestinal obstruction, alkaline phosphatase increased, diarrhea, hyperbilirubinemia, electrocardiogram QT prolonged, decreased appetite, dehydration, hypercalcemia, hyperphosphatemia, hypophosphatemia, back pain, pain in extremity, syncope, acute kidney injury, onychomadesis, and hypotension.

Dose reductions due to an adverse reaction occurred in 14% of patients who received PEMAZYRE. Adverse reactions requiring dosage reductions in ≥1% of patients who received PEMAZYRE included stomatitis, arthralgia, palmar-plantar erythrodysesthesia syndrome, asthenia, and onychomadesis.

Clinically relevant adverse reactions occurring in ≤10% of patients included fractures (2.1%). In all patients treated with pemigatinib, 0.5% experienced pathologic fractures (which included patients with and without cholangiocarcinoma

[N=635]). Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis associated with hyperphosphatemia were observed with PEMAZYRE treatment.

Within the first 21-day cycle of PEMAZYRE dosing, serum creatinine increased (mean increase of 0.2 mg/dL) and reached steady state by Day 8, and then decreased during the 7 days off therapy. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed.

In cholangiocarcinoma (n=146) the most common adverse reactions (incidence ≥20%) were hyperphosphatemia (60%), alopecia (49%), diarrhea (47%), nail toxicity (43%), fatigue (42%), dysgeusia (40%), nausea (40%), constipation (35%), stomatitis (35%), dry eye (35%), dry mouth (34%), decreased appetite (33%), vomiting (27%), arthralgia (25%), abdominal pain (23%), hypophosphatemia (23%), back pain (20%), and dry skin (20%).

Drug Interactions

Avoid concomitant use of strong and moderate CYP3A inhibitors with PEMAZYRE. Reduce the dose of PEMAZYRE if concomitant use with a strong or moderate CYP3A inhibitor cannot be avoided. Avoid concomitant use of strong and moderate CYP3A inducers with PEMAZYRE.

Special Populations

Advise lactating women not to breastfeed during treatment with PEMAZYRE and for 1 week after the last dose.

Reduce the recommended dose of PEMAZYRE for patients with severe renal impairment as described in the prescribing information.

Reduce the recommended dose of PEMAZYRE for patients with severe hepatic impairment as described in the prescribing information.

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.

You may also report side effects to Incyte Medical Information at 1-855-463-3463.

Please click here for Full Prescribing Information for PEMAZYRE.

References: 1. Data on file. Incyte Corporation. Wilmington, DE. **2.** PEMAZYRE Prescribing Information. Wilmington, DE: Incyte Corporation. **3.** Abou-Alfa GK, Sahai V, Hollebecque A, et al. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study. *Lancet Oncol*. 2020;21(5):671-684. **4.** Li F, Peiris MN, Donoghue DJ. Functions of FGFR2 corrupted by translocations in intrahepatic cholangiocarcinoma. *Cytokine Growth Factor Rev*. 2020;52:56-67. **5.** Foundation Medicine. https://info.foundationmedicine.com/hubfs/FMI%20Labels/FoundationOne_CDx_Label_Technical_Info.pdf. Accessed March 30, 2021. **6.** Mahipal A, Tella SH, Kommalapati A, Yu J, Kim R. Prevention and treatment of FGFR inhibitor-associated toxicities. *Crit Rev Oncol Hematol*. 2020;155:103091. doi: 10.1016/j.critrevonc.2020.103091. Epub ahead of print. **7.** Valle JW, Lamarca A, Goyal L, Barriuso J, Zhu AX. New Horizons for Precision Medicine in Biliary Tract Cancers. *Cancer Discov*. 2017;7(9):943-962. **8.** Lacouture ME, Sibaud V, Anadkat MJ, et al. Dermatologic Adverse Events Associated with Selective Fibroblast Growth Factor Receptor Inhibitors: Overview, Prevention, and Management Guidelines. *Oncologist*. 2021;26(2):e316-e326. **9.** American Academy of Ophthalmology. What Is Optical Coherence Tomography? https://www.aao.org/eye-health/treatments/what-is-optical-coherence-tomography. Accessed April 16, 2021. **10.** Leggit, JC. Acute and Chronic Paronychia. *Am Fam Physician*. 2017;96(1):44-51. **11.** Dorland's Medical Dictionary. Onychauxis. https://www.dorlandsonline.com/dorland/definition?id=35101&searchterm=onychauxis. Accessed October 4, 2021. **12.** Salgado F, Handler MZ, Schwartz RA. Shedding light on onychomadesis. *Cutis*. 2017;99:33-36. **13.** American Osteopathic College of Dermatology. Onycholysis. https://www.aocd.org/page/onycholysis. Accessed September 30, 2021. **14.** National Cancer Institute Dictionary. https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/nail-dystrophy. Accessed October 4, 2021. **15.** O'Brien CP. *Can Fam Physician*. 2009;55(9):891-892. **16.** US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE). https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Accessed August 10, 2021.

Please see full Important Safety Information on pages 33-39, and click here for Full Prescribing Information for PEMAZYRE.

For questions about PEMAZYRE® (pemigatinib), please contact Medical Information at 1-855-463-3463

Common Terminology Criteria for Adverse Events (CTCAE)[16]

Grades

Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on the following general guideline:

Grade 1

Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated

Grade 2

Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL)[a]

Grade 3

Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL[b]

Grade 4

Life-threatening consequences; urgent intervention indicated

Grade 5

Death related to AE

[a]Instrumental ADL refers to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

[b]Self-care ADL refers to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

Pemazyre
(pemigatinib) tablets
13.5mg • 9mg • 4.5mg

For more information on adverse reactions with PEMAZYRE, visit hcp.pemazyre.com or scan the QR code

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