PRESCRIBING INFORMATION

PEMAZYRE® ▼ (pemigatinib) 4.5, 9, 13.5 mg tablets
contains Microcrystalline cellulose (E-460), Sodium starch glycolate (Type A), Magnesium stearate (E-572).

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See below for how to report adverse reactions.

Indication: Pemazyre monotherapy is indicated for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.
Dosage and administration: The recommended dose is 13.5 mg pemigatinib taken once daily for 14 days followed by 7 days off therapy. Therapy should be initiated by a physician experienced in biliary tract cancer. Confirm FGFR2 positive status prior to starting treatment. Treatment should be continued as long as the patient does not show evidence of disease progression or unacceptable toxicity.
Contraindications: Hypersensitivity to pemigatinib or excipients. Concomitant use of pemigatinib with St John's wort.
Warnings and precautions: Consult the Summary of Product Characteristics (SmPC) for full details of potential toxicities and drug interactions, as well as information on monitoring and management, including recommended dose modifications.
Hyperphosphataemia: Hyperphosphataemia is a pharmacodynamic effect expected with pemigatinib. Effective management strategies for hyperphosphataemia include dietary phosphate restriction, phosphate-lowering therapy and dose modification. Consult the SmPC for full details.
Hypophosphataemia: Consider discontinuing phosphate-lowering therapy and increasing dietary phosphate if hypophosphataemia occurs. Consult the SmPC for full details.
Serous retinal detachment: Pemigatinib can cause serous retinal detachment reactions. Symptoms can include blurred vision, visual floaters, or photopsia. Ophthalmological examination, including optical coherence tomography (OCT) should be performed prior to starting pemigatinib and throughout treatment. Consult the SmPC for full details of OCT requirements and dose modification guidelines for serous retinal detachment reactions.
Dry eye: Pemigatinib can cause dry eye. Treat with ocular demulcents as needed.
Blood creatinine increase: Pemigatinib may increase serum creatinine by decreasing renal tubular secretion of creatinine. Alternative markers of renal function should be considered if persistent elevations in serum creatinine are observed.
Hepatic or renal impairment: Dose adjustment is recommended when administering pemigatinib to patients with severe hepatic or renal impairment.
Central nervous system (CNS) metastasis: Since untreated or progressing brain/CNS metastasis were not allowed in the study, efficacy in this population has not been evaluated and no dose recommendations can be made, however the blood-brain barrier penetration of pemigatinib is expected to be low.
Driving and operating machinery: Adverse reactions of fatigue and symptoms associated with retinal detachment may influence the ability to drive and operate machinery.
Drug interactions: If concurrent use of strong CYP3A4 inhibitors is necessary, the daily dose of pemigatinib should be reduced. Consult the SmPC for full details and for information on all potential drug interactions.
Pregnancy and breast-feeding: Pemigatinib can cause foetal harm when administered during pregnancy. Women of childbearing potential, including partners of male patients, should use effective contraception during treatment with pemigatinib and for 1 week after the last dose. Discontinue breast-feeding during treatment with pemigatinib and for 1 week following last dose.
Undesirable effects: The most common adverse drug reactions (ADRs) were hyperphosphataemia, alopecia, diarrhoea, nail toxicity, fatigue, nausea, dysgeusia, stomatitis, constipation, dry mouth, dry eye, arthralgia, hypophosphataemia, dry skin, and palmar-plantar erythrodysaesthesia syndrome. The most common serious adverse reactions were hyponatraemia and blood creatinine increase (see SmPC for details of all ADRs).

Quantities and marketing authorisation numbers:
4.5 mg dose (14 or 28 tablets) EU/1/21/1535/001-002, PLGB 42338/0008
9 mg dose (14 or 28 tablets) EU/1/21/1535/003-004, PLGB 42338/0009
13.5 mg dose (14 or 28 tablets) EU/1/21/1535/005-006, PLGB 42338/0010

Cost (ex. VAT): 4.5 mg x 14 tablets £7,159; 9 mg x 14 tablets £7,159; 13.5 mg x 14 tablets £7,159.

Legal categorisation: POM (prescription only medicine).

Marketing authorisation holder:
Great Britain: Incyte Biosciences UK Ltd, First Floor Q1, The Square, Randalls Way, Leatherhead, KT22 7TW, UK.
United Kingdom (Northern Ireland): Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Netherlands.

Date of preparation: April 2021.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Incyte immediately by phoning 0330-100-3677 (Great Britain) or 00-800-0002-7423 (United Kingdom [Northern Ireland]).