INLYTA® ▼(axitinib) – PRESCRIBING INFORMATION

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INLYTA ▼ (axitinib) Film-Coated Tablets

Please refer to the Summary of Product Characteristics (SmPC) before prescribing INLYTA 1 mg, 3 mg, 5 mg or 7 mg film-coated tablets.

▼ 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 section 4.8 of the SmPC for how to report adverse reactions.

Presentation: Each 1 mg, 3 mg, 5 mg and 7 mg film-coated tablet contains 1 mg, 3 mg, 5 mg and 7 mg of axitinib, respectively.

Indications: For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. Dosage: Treatment should be initiated by a physician experienced in the use of anticancer therapies. The recommended oral dose is 5 mg twice daily (approximately 12 hours apart) taken with or without food. Dose increase or reduction is recommended based on individual safety and tolerability. Patients who tolerate the starting dose of 5 mg twice daily with no adverse reactions > Grade 2 according to Common Terminology Criteria for Adverse Events (CTCAE) for two consecutive weeks may have their dose increased to 7 mg twice daily unless BP > 150/90 mmHg or patient is receiving anti-hypertensive medication. Subsequently, using the same criteria, patients who tolerate a dose of 7 mg twice daily, may have their dose increased to a maximum of 10 mg twice daily. Management of some adverse drug reactions may require temporary or permanent discontinuation and/or dose reduction. When dose reduction is necessary, the dose may be reduced to 3 mg twice daily and further to 2 mg twice daily. Co-administration with strong CYP3A4/5 inhibitors or inducers may increase or decrease axitinib plasma concentrations respectively. Selection of an alternative concomitant medicine with no or minimal CYP3A4/5 inhibition or induction potential is recommended. If a strong CYP3A4/5 inhibitor must be co-administered, a dose decrease of axitinib to approximately half the dose (e.g. from a starting dose of 5 mg twice daily to a reduced dose of 2 mg twice daily) is recommended. If co-administration of the strong inhibitor is discontinued, a return to the axitinib dose used prior to initiation of the CYP3A4/5 inhibitor should be considered. If a strong CYP3A4/5 inducer must be co-administered, a gradual dose increase is recommended with careful monitoring for toxicity. If coadministration of the strong inducer is discontinued the axitinib dose should be immediately returned to the dose used prior to initiation of the strong CYP3A4/5 inducer. No dose adjustment is required in elderly patients or patients with renal impairment or with mild hepatic impairment (Child Pugh class C) A). A dose decrease is recommended in patients with moderate hepatic impairment (Child-Pugh class B) (e.g. the starting dose should be reduced from 5 mg twice daily to 2 mg twice daily). Axitinib has not been studied in patients with severe hepatic impairment (Child-Pugh class C) and should not be used in this population. Dose adjustment is not required on the basis of patient age, race, gender, or body weight. Thyroid function should be monitored prior to initiation of, and periodically throughout, treatment. Hypothyroidism and, to a lesser extent, hyperthyroidism were reported in clinical studies and should be tested as per standard medical practice to maintain euthyroid status. Reflexive increase in red blood cell mass may occur during treatment and should be monitored before initiation of, and periodically throughout, treatment and treated as per standard medical practice. An increase in red blood cell mass may increase the risk of embolic and thrombotic events. Haemorrhagic events (most commonly epistaxis, haematuria, rectal haemorrhage and gingival bleeding) were reported in clinical studies. Axitinib has not been studied in patients who have evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. Temporary interrupt treatment if any bleeding requires medical intervention. Events of gastrointestinal perforation and fistulas were reported in clinical studies and symptoms for these should be monitored periodically throughout treatment. Treatment with axitinib should be stopped at least 24 hours prior to scheduled surgery and the decision to resume therapy after surgery should be based on clinical judgment of adequate wound healing. Events of posterior reversible encephalopathy syndrome (PRES) (a neurological disorder which can present with headache, seizure, lethargy, confusion, blindness and other visual and neurologic disturbances; mild to severe hypertension may be present) were reported in clinical studies. MRI is necessary to confirm diagnosis. In patients with signs or symptoms of PRES, temporarily interrupt or permanently discontinue axitinib treatment. The safety of reinitiating therapy in patients previously experiencing PRES is not known. Proteinuria, including that of Grade 3 severity, was reported in clinical studies. Monitoring for proteinuria before initiation of, and periodically throughout, treatment with axitinib is recommended. In moderate to severe proteinuria reduce the dose or temporarily interrupt treatment. Increases in ALT, AST and bilirubin have been reported. Liver function tests should be monitored before initiation of, and periodically throughout, treatment. Systemic exposure to axitinib was approximately two-fold higher in subjects with moderate hepatic impairment (Child-Pugh class B) compared to subjects with normal hepatic function. In these patients dose decrease is recommended (see Dosage section). Axitinib has not been studied in patients with severe hepatic impairment (Child-Pugh class C) and should not be used in these patients. Contains lactose and may cause foetal harm, thrombocytopenia, polycythaemia, hyperthyroidism, dehydration, hyperkalaemia, hypercalcaemia, tinnitus, venous and arterial embolic and thrombotic events, orpharyngeal pain, flatulence, haemorrhoids, glossodynia, gastrointestinal perforation and fistula, hyperbilirubinaemia, pruritus, erythema, alopecia, myalgia, renal failure, thyroid stimulating hormone increased, lipase increased, and ALT, AST, alkaline phosphatase, creatinine and amylase increased. Refer to SmPC for information on other adverse effects. Legal Category: POM. Basic NHS cost: £703.40 per pack of 56 x 1 mg tablets; £2110.20 per pack of 56 x 3 mg tablets; £3517.50 per pack of 56 x 5 mg tablets; £4923.80 per pack of 56 x 7 mg tablets. Marketing Authorisation Number: EU/1/12/777/002 - 1 mg (56 tablets); EU/1/12/777/003 - 3 mg (56 tablets); EU/1/12/777/005 - 5 mg (56 tablets); EU/1/12/777/011 - 7 mg (56 tablets) Marketing Authorisation Holder: Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom. Further information is available on request from: Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel +44 (0)1304 616161

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Pfizer Medical Information on 01346016161

Axitinib should not be used during breast-feeding and women of childbearing potential must use effective contraception during and up to 1 week after treatment. Fertility may be impaired during treatment. Driving and operating machinery: Axitinib has a minor influence on the ability to drive and use machines. Advise patients that they may experience dizziness and/or fatigue during treatment. Unsuitable effects: The most important serious adverse reactions reported in patients receiving axitinib were arterial embolic and thrombotic events, venous embolic and thrombotic events, haemorrhage (including gastrointestinal haemorrhage, cerebral haemorrhage and haemoptysis), gastrointestinal perforation and fistula formation, hypertensive crisis, and PRES. Very common (≥ 1/10) adverse events are hypothyroidism, decreased appetite, headache, dizziness, dysgeusia, hypertension, haemorrhage (epistaxis, haematuria, haemoptysis, rectal haemorrhage, gingival bleeding, gastric haemorrhage, cerebral haemorrhage, lower gastrointestinal haemorrhage), dyspnoea, cough, dysphonia, diarrhoea, vomiting, nausea, abdominal pain, stomatitis, constipation, upper abdominal pain, dyspepsia, palmar-planter erythrodysesthesia (hand-foot syndrome), rash, dry skin, arthralgia, pain in extremity, proteinuria, fatigue, ashenoma, mucosal inflammation, weight decreased. Common (∼ 1/100 to ≤ 1/10) reported adverse events are anaemia, thrombocytopenia, polycythaemia, hyperthyroidism, dehydration, hyperkalaemia, hypercalcaemia, tinnitus, venous and arterial embolic and thrombotic events, orpharyngeal pain, flatulence, haemorrhoids, glossodynia, gastrointestinal perforation and fistula, hyperbilirubinaemia, pruritus, erythema, alopecia, myalgia, renal failure, thyroid stimulating hormone increased, lipase increased, and ALT, AST, alkaline phosphatase, creatinine and amylase increased.