Northern Ireland Prescribing Information:

SCEMBLIX®▼ (asciminib) 20 mg and 40mg film-coated tablets

Important note: Before prescribing, consult Summary of Product Characteristics (SmPC).

Presentation: Each film-coated tablet contains asciminib hydrochloride, equivalent to 20mg and 40mg asciminib respectively. Contains lactose. **Indication(s)**: Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine kinase inhibitors. **Dosage and administration**: The recommended daily dose of Scemblix is 40 mg twice daily at approximately 12-hour intervals to be taken orally without food. Tablets should be swallowed whole and food consumption should be avoided for at least 2 hours before and 1 hour after taking asciminib. Tablets should not be broken, crushed or chewed. Treatment should be continued as long as clinical benefit is observed or until unacceptable toxicity occurs. If a dose is missed by more than approximately 6 hours, it should be skipped, and the next dose should be taken as scheduled. If missed by less than 6 hours, it should be taken, and the next dose taken as scheduled. *Dose modification:* For the management of adverse reactions, the dose can be reduced based on individual safety and tolerability (See Warnings & Precautions). The starting dose is 40 mg twice daily, while the reduced dose is 20 mg twice daily. Refer to the SmPC for management of selected adverse reactions.

Renal impairment: No dose adjustment is required in patients with mild, moderate or severe renal impairment. *Hepatic impairment:* No dose adjustment is required in patients with mild, moderate or severe hepatic impairment. *Paediatric population:* Safety and efficacy in paediatric patients aged below 18 years have not been established. No data are available. *Elderly:* No dose adjustment is required in patients aged 65 years or above.

Contraindications: Hypersensitivity to the active substance or to any excipients.

Warnings/Precautions: *Myelosuppression:* Treatment is associated with thrombocytopenia, neutropenia and anaemia with severe (NCI CTCAE grade 3 or 4) thrombocytopenia and neutropenia events reported during treatment. Complete blood counts should be performed every two weeks for the first 3 months of treatment and then monthly thereafter. Patients should be monitored for signs and symptoms of myelosuppression. *Pancreatic toxicity:* Patients should be monitored for signs and symptoms of pancreatic toxicity. Serum lipase and amylase levels should be assessed monthly during treatment or as clinically indicated. More frequent monitoring should be performed in patients with a history of pancreatitis. If serum lipase and amylase elevation are accompanied by abdominal symptoms, treatment should be temporarily withheld, and appropriate diagnostic tests should be considered to exclude pancreatitis. *QT prolongation:* It is recommended that an electrocardiogram is performed prior to the start of treatment and monitored during treatment as clinically indicated. Hypokalaemia and hypomagnesaemia should be corrected prior to asciminib administration and monitored during treatment as clinically indicated. Caution should be exercised when administering asciminib concomitantly with medicinal products known to cause *torsades de pointes*. *Hypertension:* Hypertension and other cardiovascular risk factors should be monitored and managed using standard antihypertensive therapy during treatment with asciminib as clinically indicated. *Hepatitis B reactivation:* Reactivation of hepatitis B virus (HBV) has occurred in patients who are chronic carriers of this virus following administration of other BCR::ABL1 tyrosine kinase inhibitors (TKIs). Patients should be tested for HBV infection before the start of treatment with asciminib. HBV carriers should be closely monitored for signs and symptoms of active HBV infection throughout therapy and for several months following termination of therapy. *Lactose:* Scemblix tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interactions:

Medicinal products that may decrease asciminib plasma concentrations:

Caution should be exercised during concomitant administration of:

• *Strong CYP3A inducers*, including, but not limited to, carbamazepine, phenobarbital, phenytoin or St. John's wort (Hypericum perforatum), which may result in lower efficacy of asciminib.

Medicinal products that may have their plasma concentrations altered by asciminib:

Caution should be exercised during concomitant administration of the following, where dose adjustment of asciminib is not required:

• CYP3A4 substrates known to have a narrow therapeutic index, including but not limited to, fentanyl, alfentanil, dihydroergotamine or ergotamine. • CYP2C9 substrates known to have a narrow therapeutic index, including but not limited to, phenytoin or warfarin

• OATP1B, BCRP substrates or substrates of both transporters: including, but not limited to sulfasalazine, methotrexate, pravastatin, atorvastatin, pitavastatin, rosuvastatin and simvastatin.

• P-gp substrates known to have a narrow therapeutic index including but not limited to digoxin, dabigatran and colchicine.

Fertility, pregnancy and lactation: Asciminib is not recommended for use during pregnancy, or in women that are sexually active of childbearing potential not using contraception. The patient should be advised of a potential risk to the foetus if asciminib is used during pregnancy or if the patient becomes pregnant while taking asciminib. Breast-feeding is not recommended during treatment and for at least 3 days after stopping treatment with asciminib. There are no data on the effect of asciminib on human fertility.

Undesirable effects: *Very common (≥1/10):* Upper respiratory tract infection, thrombocytopenia, neutropenia, anaemia, dyslipidaemia, headache, dizziness, hypertension, dyspnoea, cough, pancreatic enzymes increased, vomiting, diarrhoea, nausea, abdominal pain, hepatic enzyme increased, rash, pruritus, musculoskeletal pain, arthralgia, fatigue, oedema, pyrexia, decrease in phosphate levels. *Common (≥1/100 to <1/10):* Lower respiratory tract infection, influenza, decreased appetite, hyperglycaemia, dry eye, vision blurred, palpitations, pleural effusion, non-cardiac chest pain, pancreatitis, blood bilirubin increased, urticaria, blood creatine phosphokinase increased. *Uncommon (≥1/1,000 to <1/100):* Febrile neutropenia, pancytopenia, hypersensitivity, Electrocardiogram QT prolonged. *Other Adverse Effects:* Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing

Legal classification: POM

Marketing Authorisation (MA) number, quantities and price:

EU/1/22/1670/002– 20 mg x 60 tablet pack £4,050.37

EU/1/22/1670/004 – 40 mg x 60 tablet pack £4,050.37

Date of last revision of prescribing information: July 2024

Full Prescribing Information available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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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 Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com or call 01276 698370