Prescribing information

BRILIQUE™▼ 90MG FILM-COATED TABLETS (ticagrelor) PRESCRIBING INFORMATION. Consult Summary of Product Characteristics before prescribing. Use: Adults aged 18 years and older, co-administered with 75-150mg acetylsalicylic acid (ASA) daily: for the prevention of atherothrombotic events in patients with acute coronary syndromes (unstable angina, non-ST-segment elevation myocardial infarction [NSTEMI] or ST-segment elevation myocardial infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). **Presentation:** 90mg ticagrelor film-coated tablets. **Dosage and administration:** Treatment should be initiated with a single 180mg loading dose (two tablets of 90mg) and then continued at 90mg twice daily. Treatment is recommended for up to 12 months unless discontinuation is clinically indicated. Premature discontinuation of treatment or lapses in therapy should be avoided. Patients treated with clopidogrel can be directly switched to Brilique. For oral use. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active pathological bleeding. History of intracranial haemorrhage. Moderate-to-severe hepatic impairment. Co-administration with strong CYP3A4 inhibitors (e.g. ketoconazole). **Precautions:** Due to the increased risk of non-fatal or non-life-threatening bleeding, use with caution in patients at an increased risk for bleeding (e.g. recent trauma or surgery, bleeding disorders or recent gastrointestinal bleeding) or those on concomitant medication that may increase bleeding risk (e.g. NSAIDs, anticoagulants) within 24 hours of taking Brilique. Brilique should be stopped 7 days prior to elective surgery if the antiplatelet effect is not desired. Use with caution in patients with an increased risk of bradycardic events (e.g. patients on digoxin), as asymptomatic ventricular pauses have been observed with Brilique, a history of asthma and/or COPD, a history of hyperuricaemia or gouty arthritis. Creatinine levels may increase during treatment with Brilique. Renal function should be checked after one month and thereafter according to routine medical practice, paying special attention to patients ≥ 75 years, patients with moderate-to-severe renal impairment and those receiving concomitant treatment with an ARB. Co-administration of Brilique is not recommended with a high maintenance dose of ASA (> 300mg) or with doses of simvastatin > 40mg. Co-administration of ticagrelor with strong CYP3A4 inducers is discouraged, as this may lead to a decrease in exposure and efficacy of ticagrelor. Brilique is not recommended during pregnancy and breastfeeding. **Undesirable events**: Common side effects include dyspnoea, epistaxis, gastrointestinal haemorrhage, subcutaneous or dermal bleeding, bruising and procedural site haemorrhage. Other adverse events include intracranial bleeding, elevations of serum creatinine and uric acid levels. **Consult SmPC for a full list of adverse events. Legal category:** POM. **Marketing authorisation number:** EU/1/10/655/004. **Basic NHS cost:** Brilique 90mg film-coated tablets, 56: £54.60. **Further information is available from:** AstraZeneca UK Ltd., 600 Capability Green, Luton, LU1 3LU. BRILIQUE is a trademark of the AstraZeneca group of companies. 11/2010 CV 10 0118

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk Adverse events should also be reported to AstraZeneca on 0800 783 0033

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