23 September 2010
EMA/536945/2010
Committee for medicinal products for human use (CHMP)

## Summary of opinion[1] (initial authorisation)

# Brilique

## Ticagrelor

On 23 September 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Brilique 90mg film-coated tablets. Brilique, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]) including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). The applicant for this medicinal product is AstraZeneca AB. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Brilique is ticagrelor, a member of the chemical class cyclopentyltriazolopyrimidines (CPTP), which is a selective and reversible binding adenosine diphosphate (ADP) receptor antagonist acting on the $P2Y_{12}$ ADP-receptor that can prevent ADP-mediated platelet activation and aggregation.

The benefits with Brilique are its ability to rapidly and reversibly inhibit platelet aggregation and through this to prevent thrombotic events in patients with acute coronary syndromes. The most common side effects are dyspnoea, contusion and epistaxis.

A pharmacovigilance plan for Brilique will be implemented as part of the marketing authorisation.

The approved indication is: “Brilique, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).”

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Brilique and therefore recommends the granting of the marketing authorisation.

| MA (EU) number | (Invented) name | Strength | Pharmaceutical Form | Route of Administration | Immediate Packaging | Pack size |
|---|---|---|---|---|---|---|
| EU/1/10/655/001 | Brilique | 90 mg | Film-coated tablet | Oral use | blister (PVC/PVDC/alu) | 60 tablets |
| EU/1/10/655/002 | Brilique | 90 mg | Film-coated tablet | Oral use | blister (PVC/PVDC/alu) | 180 tablets |
| EU/1/10/655/003 | Brilique | 90 mg | Film-coated tablet | Oral use | calendar blister (PVC/PVDC/alu) | 14 tablets |
| EU/1/10/655/004 | Brilique | 90 mg | Film-coated tablet | Oral use | calendar blister (PVC/PVDC/alu) | 56 tablets |
| EU/1/10/655/005 | Brilique | 90 mg | Film-coated tablet | Oral use | calendar blister (PVC/PVDC/alu) | 168 tablets |
| EU/1/10/655/006 | Brilique | 90 mg | Film-coated tablet | Oral use | blister (PVC/PVDC/alu) | 100 x 1 tablet (unit dose) |
| EU/1/10/655/007 | Brilique | 60 mg | Film-coated tablet | Oral use | calendar blister (PVC/PVDC/alu) | 14 tablets |
| EU/1/10/655/008 | Brilique | 60 mg | Film-coated tablet | Oral use | calendar blister (PVC/PVDC/alu) | 56 tablets |
| EU/1/10/655/009 | Brilique | 60 mg | Film-coated tablet | Oral use | blister (PVC/PVDC/alu) | 60 tablets |
| EU/1/10/655/010 | Brilique | 60 mg | Film-coated tablet | Oral use | calendar blister (PVC/PVDC/alu) | 168 tablets |
| EU/1/10/655/011 | Brilique | 60 mg | Film-coated tablet | Oral use | blister (PVC/PVDC/alu) | 180 tablets |

| MA (EU) number | (Invented) name | Strength | Pharmaceutical Form | Route of Administration | Immediate Packaging | Pack size |
|---|---|---|---|---|---|---|
| EU/1/10/655/012 | Brilique | 90 mg | Orodispersible tablet | Oral use | blister (alu/alu) | 10 x 1 tablets (unit dose) |
| EU/1/10/655/013 | Brilique | 90 mg | Orodispersible tablet | Oral use | blister (alu/alu) | 56 x 1 tablets (unit dose) |
| EU/1/10/655/014 | Brilique | 90 mg | Orodispersible tablet | Oral use | blister (alu/alu) | 60 x 1 tablets (unit dose) |