



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2022
EMA/862230/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Iscover clopidogrel

On 10 November 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Iscover. The marketing authorisation holder for this medicinal product is sanofi-aventis groupe.

The CHMP adopted a change to the existing indication to include the secondary prevention of atherothrombotic events in patients with ST segment elevation acute myocardial infarction (STEMI) in patients undergoing percutaneous coronary intervention (PCI):

For information, the full indications for Iscover will be as follows²:

Secondary prevention of atherothrombotic events

Clopidogrel is indicated in:

- Adult patients suffering from myocardial infarction (from a few days until less than 35 days), ischemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease.
- Adult patients suffering from acute coronary syndrome:

Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA).

ST segment elevation acute myocardial infarction, in combination with ASA **in patients undergoing percutaneous coronary intervention (including patients undergoing a stent placement) or** in medically treated patients eligible for thrombolytic/fibrinolytic therapy.

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

² New text in bold



In patients with moderate to high-risk Transient Ischemic Attack (TIA) or minor Ischemic Stroke (IS) Clopidogrel in combination with ASA is indicated in:

-Adult patients with moderate to high-risk TIA (ABCD2³ score ≥ 4) or minor IS (NIHSS⁴ ≤ 3) within 24 hours of either the TIA or IS event.

Prevention of atherothrombotic and thromboembolic events in atrial fibrillation

In adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.

For further information please refer to section 5.1.

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

³ Age, Blood pressure, Clinical features, Duration, and Diabetes mellitus diagnoses

⁴ National Institutes of Health Stroke Scale