



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2026
EMADOC-1700519818-3050557
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Inaqovi

decitabine / cedazuridine

On 23 April 2026, 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 Inaqovi. The marketing authorisation holder for this medicinal product is Otsuka Pharmaceutical Netherlands B.V.

The CHMP adopted a new indication as follows:²

Inaqovi is indicated as monotherapy for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy.

Inaqovi in combination with venetoclax is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy.

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

¹ Summary 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

