17 September 2026
EMADOC-1700519818-3429056
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Keytruda
pembrolizumab

On 17 September 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 Keytruda. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted a change to an existing indication as follows:[2]

> KEYTRUDA, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC)~~ who are ineligible for cisplatin-containing chemotherapy~~.

The full indications for Keytruda are available in the summary of product characteristics (SmPC) on EMA website.

Detailed recommendations for the use of this product will be described in the updated 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] 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] Removed text as strikethrough.

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