21 May 2026
EMADOC-1700519818-3170644
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Keytruda

pembrolizumab

On 21 May 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 (SC formulation). The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted extensions to three indications for Keytruda solution for injection as follows:[2]

> KEYTRUDA as monotherapy is indicated for the treatment of adults **and adolescents aged 12 years and older** with advanced (unresectable or metastatic) melanoma.
>
> KEYTRUDA as monotherapy is indicated for the adjuvant treatment of adults **and adolescents aged 12 years and older** with Stage IIB, IIC or III melanoma and who have undergone complete resection (see section 5.1).
>
> KEYTRUDA as monotherapy is indicated for the treatment of adults **and adolescents aged 12 years and older** with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.

These indications are already authorised for Keytruda concentrate for solution for infusion.

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

For information, on 21 May 2026 the CHMP also adopted a new indication for Keytruda in combination with enfortumab vedotin for the neoadjuvant treatment, followed by adjuvant treatment after radical cystectomy, of adults with resectable muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy. Further information is available in a dedicated summary of opinion on the EMA website.

[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.