27 February 2025
EMA/CHMP/65082/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Prevymis

letermovir

On 27 February 2025, 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 Prevymis. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted extensions to the existing indications to extend the use of Prevymis to children, and a new pharmaceutical form with two new strengths: Prevymis 20 mg and 120 mg granules in sachets.

The full indications for Prevymis film-coated tablets will be as follows:[2]

> PREVYMIS is indicated for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult **and paediatric patients weighing at least 15 kg who are** CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT).
>
> PREVYMIS is indicated for prophylaxis of CMV disease in CMV-seronegative adult~~s~~ **and paediatric patients weighing at least 40 kg** who have received a kidney transplant from a CMV-seropositive donor [D+/R-].
>
> Consideration should be given to official guidance on the appropriate use of antiviral agents.

The full indications for Prevymis concentrate for solution for infusion and granules in sachets will be as follows:**Error! Bookmark not defined.**

> PREVYMIS is indicated for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult **and paediatric patients weighing at least 5 kg who are** CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT).
>
> PREVYMIS is indicated for prophylaxis of CMV disease in CMV-seronegative adult~~s~~ **and paediatric patients weighing at least 40 kg** who have received a kidney transplant from a CMV-seropositive donor [D+/R-].
>
> Consideration should be given to official guidance on the appropriate use of antiviral agents.

[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, removed text as strikethrough

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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.