25 July 2024
EMA/331897/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Spevigo

spesolimab

On 25 July 2024, 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 Spevigo. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a new indication and an extension to an existing indication as follows: [2]

> **Spevigo is indicated for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.**
>
> Spevigo is indicated for the treatment of ~~flares in adult patients with~~ generalised pustular psoriasis (GPP) **flares in adults and adolescents from 12 years of age** as monotherapy.

For information, the full indications for Spevigo will be as follows:

> Spevigo is indicated for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.
>
> Spevigo is indicated for the treatment of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age as monotherapy.

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 made available 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] New text in bold, removed text as strikethrough

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