28 June 2018
EMA/CHMP/229070/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rapamune

sirolimus

On 28 June 2018, 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 Rapamune. The marketing authorisation holder for this medicinal product is Pfizer Limited.

The CHMP adopted a new indication as follows:

> "Rapamune is indicated for the treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function (see sections 4.2 and 5.1)"

For information, the full indications for Rapamune will be as follows:[2]

> "Rapamune is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a renal transplant. It is recommended that Rapamune be used initially in combination with ciclosporin microemulsion and corticosteroids for 2 to 3 months. Rapamune may be continued as maintenance therapy with corticosteroids only if ciclosporin microemulsion can be progressively discontinued (see sections 4.2 and 5.1).
>
> **Rapamune is indicated for the treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function (see sections 4.2 and 5.1).**"

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 will be 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

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