20 July 2017
EMA/CHMP/431002/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Signifor

pasireotide

On 20 July 2017, 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 Signifor. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted an extension to the existing indication of its intramuscular formulations (10, 20, 30, 40, mg powder and solvent for suspension for injection) as follows:[2]

> "Treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue.
>
> **Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.**"

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, removed text as strikethrough.

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