25 September 2014
EMA/CHMP/524720/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Signifor

pasireotide

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Signifor. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:
"Signifor is indicated for the 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".

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

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

Signifor 0.3 mg, 0.6 mg, 0.9 mg

Signifor is indicated for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.

Signifor 20 mg, 40 mg, 60 mg

Signifor is indicated for the 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.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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