European Medicines Agency
Evaluation of Medicines for Human Use

London, 25 June 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
SIFROL

International Nonproprietary Name (INN): ***pramipexole***

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend the variation to the terms of the marketing authorisation for the medicinal product Sifrol. The Marketing Authorisation Holder for this medicinal product is Boehringer Ingelheim International GmbH.

The extension adopted by the CHMP is to add a new pharmaceutical form associated with new strengths (0.26 mg, 0.52 mg, 1.05 mg, 2.1 mg and 3.15 mg prolonged-release tablets) to the existing product range.

The new pharmaceutical form and new strengths will be used in treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa. Prolonged-release tablets will be used once daily.

The indication adopted by the CHMP is, as follows:

SIFROL is indicated for treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations).

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) 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.

[*] 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.

[**] Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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