European Medicines Agency
Evaluation of Medicines for Human Use

London, 24 April 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
NEUPRO

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

On 24 April 2008, 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 Neupro 1mg/24h, 2mg /24h and 3mg/24h transdermal patches. The Marketing Authorisation Holder for this medicinal product is Schwarz Pharma Ltd.

The CHMP adopted a new indication as follows:
"Neupro is indicated for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults".

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.

For information, the full indications for Neupro 2mg /24h transdermal patches will be as follows***:

Restless Legs Syndrome
Neupro is indicated for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults.

Parkinson's disease
Neupro is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. 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).

* 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.

*** The text in bold represents the new or the amended indication.

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