European Medicines Agency
*Evaluation of Medicines for Human Use*

London, Thursday 24 September 2009
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**POST-AUTHORISATION SUMMARY OF POSITIVE OPINION***
**for**
**CORLENTOR/PROCOROLAN**

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

On 24 September 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 products Corlentor/Procorolan. The Marketing Authorisation Holder for this medicinal product is Les Laboratoires Servier.

The CHMP adopted a new indication as follows:
Ivabradine is indicated :
in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.

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 indication(s) for Corlentor/Procorolan will be as follows***:

Symptomatic treatment of chronic stable angina pectoris in coronary artery disease patients with normal sinus rhythm.
Ivabradine is indicated :
- in patients unable to tolerate or with a contra-indication to the use of beta-blockers
- or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.

* 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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