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Press Office

Press release

Janssen-Cilag International NV withdraws its marketing authorisation application for Comfyde (carisbamate)

The European Medicines Agency has been formally notified by Janssen-Cilag International NV of its decision to withdraw its application for a centralised marketing authorisation for the medicine Comfyde (carisbamate) 100mg, 200mg, 400mg and 600mg film-coated tablets.

This medicine was intended to be used for adjunctive treatment of partial onset seizures with or without secondary generalisation in patients aged 16 years or older.

The application for the marketing authorisation for Comfyde was submitted to the Agency on 27 August 2009. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that its decision to withdraw the application was based on the feedback from the CHMP indicating that the Committee is unlikely to reach a favourable opinion without additional efficacy data, which at this time cannot be provided.

More information about Comfyde and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the next CHMP meeting on 18-21 January 2010.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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