JANSSEN-CILAG
INTERNATIONAL NV

Dr Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB

15th January 2010

Subject: Withdrawal of COMFYDE, (carisbamate), 100mg, 200mg, 400mg and 600mg film-coated tablets

EMEA/H/C/1221

Dear Dr Abadie

I would like to inform you that Janssen-Cilag International NV has made the decision to withdraw the application for Marketing Authorisation of COMFYDE (carisbamate) 100mg, 200mg, 400mg and 600 mg film-coated tablets, which was to be used for adjunctive treatment of partial onset seizures with or without secondary generalisation in patients 16 years or older.

The decision was made by Janssen-Cilag International NV on the basis of preliminary comments from the Rapporteur and Co-Rapporteur which indicate that CHMP is unlikely to conclude a favourable approval decision without additional efficacy data which at this time cannot be provided.

As a consequence, and in line with Good Clinical Practice, Janssen-Cilag International NV will discontinue all currently ongoing clinical trials with carisbamate for the adjunctive treatment of partial onset seizures.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

This letter may be published on the EMEA website.

Yours sincerely

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