European Medicines Agency

London, 29 September 2004
EMEA/90947/04

PUBLIC STATEMENT ON
IXENSE (Apomorphine Hydrochloride)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 28 May 2001 the European Commission granted a marketing authorisation for the whole European Union to Takeda Europe R&D Centre Ltd, for Ixense (apomorphine hydrochloride), indicated for the treatment of erectile dysfunction.

Ixense has been marketed in Austria, Germany, France and Italy. On 23 August 2004 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for Ixense for commercial reasons. There is still one Community Marketing Authorisation valid throughout the European Union for medicinal products containing apomorphine hydrochloride i.e. Uprima.

On 28 September 2004 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Ixense". Pursuant to this decision the European Public Assessment Report for Ixense has been removed from the EMEA website.

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