6 June 2011
EMA/427975/2011
Human Medicines Development and Evaluation

Public statement

Agenerase (amprenavir)

Withdrawal of the marketing authorisation in the European Union

On 20 October 2000 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Agenerase (amprenavir). Agenerase had been approved in combination with other antiretroviral agents for the treatment of protease inhibitor (PI) experienced HIV-1 infected adults and children above the age of 4 years.

The marketing authorisation holder (MAH) responsible for Agenerase was Glaxo Group Ltd. The European Commission was notified by letter dated 17 December 2009 of the MAH's decision to voluntarily withdraw the marketing authorisation for Agenerase for commercial reasons.

Agenerase had not been marketed anywhere in the European Union since the end of 2008.
On 29 April 2010 the European Commission issued a decision to withdraw the marketing authorisation for Agenerase. Pursuant to this decision the European Public Assessment Report for Agenerase will be updated to reflect that the marketing authorisation is no longer valid.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union