EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Public statement on

Ablavar[1] (gadofosveset)

Withdrawal of the marketing authorisation in the European Union

On 3 October 2005 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Vasovist (gadofosveset) for contrast-enhanced magnetic resonance angiography (CE-MRA) for visualisation of abdominal or limb vessels in adults only, with suspected or known vascular disease. The name of the medicinal product was changed to Ablavar on 10 January 2011.

The marketing authorisation holder (MAH) responsible for Ablavar was TMC Pharma Services Ltd. The European Commission was notified by a letter dated 13 September 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Ablavar for commercial reasons. Ablavar was not marketed in any European country.

On 18 October 2011 the European Commission issued a decision to withdraw the marketing authorisation for Ablavar.

Pursuant to this decision the European Public Assessment Report for Ablavar will be updated to reflect that the marketing authorisation is no longer valid.

[1] Previously known as Vasovist.

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