The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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PUBLIC STATEMENT ON
ZARTRA (Imiquimod)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 18 September 1998 the European Commission granted a marketing authorisation for the whole European Union to Laboratoires 3M Santé for the medicinal products ALDARA and ZARTRA (both containing the active substance, imiquimod), indicated for topical treatment of external genital and perianial warts (condyloma acuminata) in adult patients.

On 12 April 2002 the Marketing Authorisation Holder notified the European Commission of his decision to voluntarily withdraw the Marketing Authorisation for ZARTRA for commercial reasons. ZARTRA has never been marketed in the European Union. ALDARA continues to be available and is marketed in all European Member States.

On 11 June 2002 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "ZARTRA". Pursuant to this decision the European Public Assessment Report for ZARTRA has been removed from the EMEA website.

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