



The European Agency for the Evaluation of Medicinal Products
Post-authorisation Evaluation of Medicines for Human Use

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**PUBLIC STATEMENT ON
OPULIS (Desloratadine)**

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 15 January 2001 the European Commission granted a marketing authorisation for the whole European Union to SP Europe, for Opulis (desloratadine), indicated for the relief of symptoms associated with allergic rhinitis (AR) and with chronic idiopathic urticaria (CIU).

Opulis was not marketed anywhere in the European Union. On 2 February 2004 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for Opulis for commercial reasons. There are still three Community Marketing Authorisations valid throughout the European Union for medicinal products containing desloratadine i.e. Aerius, Azomyr and Neoclarityn.

On 10 March 2004 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Opulis". Pursuant to this decision the European Public Assessment Report for Opulis has been removed from the EMA website.

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