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

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PUBLIC STATEMENT ON
TROVAN / TROVAN IV / TURVEL / TURVEL IV

WITHDRAWAL OF THE MARKETING AUTHORISATIONS

- The European Commission granted Marketing Authorisations valid throughout the European Union to Pfizer Limited on 3 July 1998 for TROVAN (trovafloxacin) and TROVAN IV (alatrofoxacin), and to Roerig Farmaceutici Italiana S.p.A. on 8 July 1998 for TURVEL (trovafloxacin) and on 3 July 1998 for TURVEL IV (alatrofloxacin).
- On 23 October 2000, the Marketing Authorisation Holders notified the European Commission of their decision to withdraw voluntarily the Marketing Authorisations for Trovan/ Trovan IV/ Turvel/ Turvel IV.
- On 20 March 2001, the European Commission adopted the decisions withdrawing the Marketing Authorisations for the medicinal products for human use Trovan/ Trovan IV/ Turvel/ Turvel IV. Pursuant to this decision the European Public Assessment Reports for Trovan/ Trovan IV/ Turvel/ Turvel IV have been removed from the EMEA website.

For further information:

- The Marketing Authorisations of Trovan/ Trovan IV/ Turvel/ Turvel IV were suspended by the European Commission on 10 August 1999, following increasing concerns over 152 documented reports of cases of serious hepatic events, including 9 cases where patients died or required a liver transplant (see Public statement EMEA/18046/99 dated 15 June 1999). Trovan/ Trovan IV/ Turvel/ Turvel IV could no longer be safely maintained in normal clinical usage due to the occurence of severe, serious and unpredictable hepatic injuries. Taking into consideration this hepatotoxicity, the overall benefit/risk balance of alatrofloxacin/ trovafloxacin was considered to be unfavourable in the authorised indications and it was not felt possible to restrict the indications adequately to permit safe use.

  The suspensions of the Marketing Authorisations were renewed by the European Commission on 12 September 2000.
- Trovan / Trovan IV have been marketed in eight member states, (Austria, Denmark, Finland, Germany, Netherlands, Portugal, Spain and Sweden). Turvel had been marketed in one member state, Spain and Turvel IV had never been marketed within the European Economic Area.

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