Steps taken for the assessment of the product

- The CVMP accepted on 8 – 10 September 1998 that Merial was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part A of the Annex to that Regulation.
- The company Merial submitted an application to the EMEA on 3 November 1998 for the granting of a Community marketing authorisation for IBRAXION in accordance with Council Regulation (EEC) No 2309/93.
- The application was validated on 17 November 1998.
- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 22 January 1999 and 10 February 1999.
- The consolidated list of questions as agreed by the CVMP during its meeting held 16 – 18 March 1999 was sent to the Applicant on 17 March 1999 at which time the clock was stopped.
- The Applicant circulated the responses to the CVMP list of questions for IBRAXION by 12 August 1999 at which point the clock was restarted.
- The joint Rapporteur and Co-rapporteur's assessment report on the responses to the consolidated list of questions, the overview of the scientific data and the overall conclusions were circulated to all CVMP Members on 9 September 1999.
- The joint Rapporteur and Co-rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 9 –11 November 1999. The CVMP considered that the answers provided addressed satisfactorily the points raised in the list of questions.
- The CVMP in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 10 November 1999 a positive opinion for the granting of a Community marketing authorisation for Ibraxion.

Manufacturing authorisations and inspection status

Manufacturer of the active substance :

Merial, Laboratory of Lyon Gerland
254, rue Marcel Mérieux
69007 Lyon

Manufacturer and assembler of the finished product:

Blending and filling :

Merial, Laboratory of Porte des Alpes
Rue de l’aviation
69800 Saint Priest

Merial, Laboratory of Lyon Gerland
254, rue Marcel Mérieux
69007 Lyon

Packaging:

Merial, Laboratory of Lentilly
Chemin du Cruzol, B.P. 8
69595 Lentilly Cedex

Manufacturer of the medicinal product responsible for batch release :

Merial
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 Saint Priest
France

CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

PROHIBITION OF SALE, SUPPLY AND/OR USE

According to Article 4 of Council Directive 90/677/EEC Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

STATEMENT OF THE MRLs

which are/may be accepted in accordance with Council Regulation (EEC) No 2377/90 and in accordance with Article 31 (3b) of Council Regulation (EEC) No 2309/93 of 22 July 1993, as amended.

The Committee for Veterinary Medicinal Products has recommended the inclusion of mineral oil in Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Mineral hydrocarbons, low to high viscosity, including microcrystalline waxes, approximately C10-C60, aliphatic, branched aliphatic and alicyclic compounds	All food producing species	Excludes aromatic and unsaturated compounds