



**OPINION OF THE COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE  
ON THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS**

PROCEDURE No EU/09/167/MER

**Name of the substance:** Methylprednisolone (INN)

**Basis for the opinion**

Pursuant to Article 6 of Council Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Merial SAS submitted to the EMEA on 2 April 2009 an application for the establishment of maximum residue limits for methylprednisolone in bovine milk.

**Recommendation**

The Committee, having considered the application, recommends by consensus the establishment of a provisional maximum residue limit for methylprednisolone in bovine milk, in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Methylprednisolone	Methylprednisolone	Bovine	2 µg/kg	Milk	Provisional MRL expires on 01.07.2011	Corticoids / Glucocorticoids

and the modification of the “Other provisions” for the existing MRLs for methylprednisolone in order to remove the provision “Not for use in animals from which milk is produced for human consumption”, in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg	Muscle Fat Liver Kidney		Corticoids / Glucocorticoids

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European Public MRL Assessment Report (EPMAR), provided in Annex I of this opinion.

The preliminary analytical method for monitoring of residues is appended to this opinion.

The present Opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 15 July 2009

*Signature on file*

Dr. G. Moulin  
Chairman, on behalf of the CVMP

**ANNEX I**

**European Public MRL Assessment Report**  
**[\(EPMAR\)](#)**