

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

FLUMEQUINE

(Extension to all food producing species)

SUMMARY REPORT (4)

1. Flumequine is a second generation quinolone antibiotic which is currently entered into Annex I of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flumequine	Flumequine	Bovine	200 µg/kg 300 µg/kg 500 µg/kg 1500 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	
		Ovine	200 µg/kg 300 µg/kg 500 µg/kg 1500 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
		Porcine	200 µg/kg 300 µg/kg 500 µg/kg 1500 µg/kg	Muscle Skin + fat Liver Kidney	
		Chicken	400 µg/kg 250 µg/kg 800 µg/kg 1000 µg/kg	Muscle Skin +fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		Turkey	400 µg/kg 250 µg/kg 800 µg/kg 1000 µg/kg	Muscle Skin +fat Liver Kidney	
		Salmonidae	600 µg/kg	Muscle and skin in natural proportions	

2. Following concern that an insufficient number of medicinal products was available to treat diseases occurring in animals, and especially diseases occurring in minor animal species, the CVMP conducted a review of the risk assessment approach for the establishment of MRLs and adopted a Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMA/CVMP/187/00-FINAL). The Note for Guidance allows for an extrapolation of MRLs to all food producing species, where identical or slightly different MRLs (i.e. MRL values normally in the same order of magnitude) have been set in cattle (or sheep), pigs and chicken (or poultry).

3. The MRLs already established for flumequine fulfil the above criteria. The MRLs are similar but not identical and it was not considered necessary to reduce the MRLs already established to the lowest values, in order to safeguard consumer safety. The existing MRLs for chickens and turkeys are identical and it was considered appropriate to extend these MRLs to poultry. It was also considered appropriate to extend the MRLs for Salmonidae to fin fish. Except for the lack of an MRL for ovine milk, the existing MRLs for bovine, ovine and porcine are identical. Therefore, it was considered appropriate to recommend extension of the lowest existing MRL values to all food producing species except for bovine, ovine, porcine, poultry and fin fish.
4. An analytical method for monitoring residues of flumequine in the edible tissues of bovine, ovine, porcine, chicken, turkeys and Salmonidae and in bovine milk was available. An assessment of the applicability of this method indicated that extrapolation to the tissues and milk of other species should not be problematic.

Conclusions and recommendation

Having considered that:

- a microbiological ADI of 495 µg/person was previously established for flumequine,
- MRLs have previously been established in bovine, ovine and porcine species and in chickens and turkeys and Salmonidae; these MRLs are of the same order of magnitude,
- an analytical method for the monitoring of residues in tissues and milk was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of flumequine in Annex I of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flumequine	Flumequine	Bovine, ovine, caprine	200 µg/kg 300 µg/kg 500 µg/kg 1500 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	
		Porcine	200 µg/kg 300 µg/kg 500 µg/kg 1500 µg/kg	Muscle Skin + fat Liver Kidney	
		Poultry	400 µg/kg 250 µg/kg 800 µg/kg 1000 µg/kg	Muscle Skin +fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		Fin fish	600 µg/kg	Muscle and skin in natural proportions	
		All food producing species except bovine, ovine, caprine, porcine, poultry and fin fish	200 µg/kg 250 µg/kg 500 µg/kg 1000 µg/kg	Muscle Fat Liver Kidney	

It was estimated that extending the MRLs to all food producing species, as proposed above, would result in a consumer intake not exceeding 82% of the ADI.