



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

DANOFLOXACIN

(Extension to all food producing species)

SUMMARY REPORT (6)

1. Danofloxacin is a fluoroquinolone 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
Danofloxacin	Danofloxacin	Bovine	200 µg/kg 100 µg/kg 400 µg/kg 400 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	
		Porcine	100 µg/kg 50 µg/kg 200 µg/kg 200 µg/kg	Muscle Skin + fat Liver Kidney	
		Chicken	200 µg/kg 100 µg/kg 400 µg/kg 400 µg/kg	Muscle Skin +fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption

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 (EMEA/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 danofloxacin fulfil the above criteria. The existing MRLs are not identical and so it was not possible to recommend modification of the entry in Annex I in such a way that the same MRLs values would apply to all food producing species. The lowest MRLs were established for porcine species but it was not considered necessary to reduce the existing MRL values to the lowest values, in order to guarantee consumer safety. Therefore it was considered appropriate to recommend extension of the existing MRLs for bovine species also to ovine and caprine species, extension of the existing MRLs for chicken tissues to poultry tissues and extension of the existing MRLs for porcine tissues to all food producing species except bovine, ovine, caprine and poultry.

4. An analytical method for monitoring residues of danofloxacin in bovine, porcine and chicken tissues 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 toxicological ADI of 1440 µg/person was previously established for danofloxacin,
- MRLs have previously been established in bovine and porcine species and in chickens; these MRLs are in 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 danofloxacin 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
Danofloxacin	Danofloxacin	Bovine, ovine, caprine	200 µg/kg 100 µg/kg 400 µg/kg 400 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	
		Poultry	200 µg/kg 100 µg/kg 400 µg/kg 400 µg/kg	Muscle Skin +fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		All food producing species except bovine, ovine, caprine and poultry	100 µg/kg 50 µg/kg 200 µg/kg 200 µg/kg	Muscle* Fat ** Liver Kidney	

* For fin fish this MRL relates to “muscle and skin in natural proportions”

** For porcine species this MRL relates to “skin and fat in natural proportions”

It was estimated that extending the MRLs to all food producing species, as proposed above, would result in a consumer intake not exceeding 52% of the ADI.