The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

PRAZIQUANTEL (extension to horses)

SUMMARY REPORT

1. Praziquantel is an anthelmintic used in both human and veterinary medicine. It is included in Annex II of Council Regulation (EEC) No 2377/90 for use is non-lactating sheep. The ADI was established at 0-0.17 mg/kg bw.

Pharmacologically active substance(s)	Animal species	Other provisions
Praziquantel	Ovine	For use in non-lactating sheep only

2. Praziquantel has been proposed for use in the minor species horses. The recommended dose is 1 mg/kg bw orally as a single treatment.

3. The plasma concentration profile in horses treated orally with ^{14}C-praziquantel showed that maximum plasma concentrations were reached approximately 30 minutes after treatment with 1 mg/kg bw. The peak plasma concentration was 0.127 mg equivalents/ml while the 24 hour mean plasma levels was 0.014 µg equivalents/ml. Urinary excretion accounted for 31% of the administered dose within 24 hours while faecal excretion accounted for a further 24% of the dose.

4. The metabolism of praziquantel has not been investigated in horses. Radiolabelled studies with ^{14}C-praziquantel in rats, dogs, monkeys and sheep show rapid and extensive metabolism with no unmetabolised compound present in any of the excretion products. All major metabolites were hydroxylated derivatives of the parent compound. Metabolism data in man also indicated rapid and extensive metabolism.

5. Praziquantel was well tolerated in horses at the recommended dose of 1 mg/kg bw but was not tested at higher dose levels.

6. Two groups of 4 horses were administered ^{14}C-praziquantel in a commercial formulation at 1 mg/kg bw as a single dose and slaughtered after 8 or 24 hours. At 8 hours post treatment, the maximum levels present in tissues were as follows: 2.44 µg equivalents/g in liver, 1.62 µg equivalents/g in kidneys, 0.14 µg equivalents/g in muscle and 0.12 µg equivalents/g in fat. At 24 hours post treatment, the maximum levels present in tissues were as follows: 0.36 µg equivalents/g in liver, 0.18 µg equivalents/g in kidneys, 0.02 µg equivalents/g in muscle, and less than 0.01 µg equivalents/g in fat.

7. At 8 hours after the end of treatment of horses with 1 mg praziquantel/kg bw, the daily intake of residues present in edible tissues is calculated to be 379 µg which represents less than 4% of the toxicological ADI (10 mg/person/day). By 24 hours the total residue which would be ingested (51 µg) is less than 1% of the ADI.

8. Therefore, the use of praziquantel in horses should not result in residues in edible tissues at concentrations, which are toxicologically relevant for the safety of the consumer.

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Conclusions and recommendation

Having considered that:

- praziquantel is rapidly excreted in horses and the calculated daily intake of residues at 8 hours post treatment represents less than 4% of the ADI,
- praziquantel is used infrequently in a small number of animals in single doses on an individual basis,
- praziquantel residues are not likely to be of toxicological concern to humans;

the Committee considers that there is no need to establish a MRL for praziquantel and recommends its inclusion in Annex II to Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Praziquantel	Equidae	