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

EMEA/MRL/240/97-FINAL
July 1997

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

POTASSIUM ASPARTATE

SUMMARY REPORT

1. Potassium aspartate (Potassium D,L-aspartate, CAS 14007-45-5) is used with other salts in the treatment of myopathy and muscular dystrophy in young cattle, sheep and pigs. It is given by intravenous, subcutaneous or intramuscular administration. The indicated dose is 2 mg/kg bw.

2. The potassium cation is an essential electrolyte that is important for the maintenance of intracellular osmotic pressure and for the maintenance of cell membrane potentials, particularly in electrically excitable tissues. It is a normal component of the diet and is particularly abundant in fruit and vegetables. The recommended daily intake varies from 350-1275 mg in children to 1875 and 5625 mg in adults. In the United Kingdom, the reference nutrient intake (RNI) is 3500 mg/day for adults.

3. The potassium ion itself possesses almost no toxicity; any toxicity of the salts is associated with the anion. Potassium aspartate is well absorbed after oral administration to humans. Potassium is excreted mainly by the kidneys; the capacity of the kidneys to conserve potassium is poor and urinary excretion continues even when there is severe bodily depletion.

4. L-Aspartate is a naturally occurring amino acid which is present in plants and animals. It is formed from oxaloacetate in a transamination reaction with glutamate as the amino donor. It is a neurotransmitter. Aspartate is metabolised by a number of complex pathways including the tricarboxylic acid cycle. It is also converted to fumarate in the urea cycle.

5. Potassium aspartate was shown to be of low acute toxicity. Acute oral LD_{50} values in the rat were 7937, 4061 and 667 mg/kg bw following oral, subcutaneous and intravenous dosing respectively.

6. The closely-related substance, magnesium aspartate has already been placed in Annex II of Council Regulation (EC) 2377/90 for all food-producing species.

Conclusions and recommendation

Having considered the criteria for the inclusion of substances in Annex II of Council Regulation (EEC) No. 2377/90 and in particular that:

- potassium aspartate is used in individual animals, on an infrequent basis;
- both potassium and aspartate are normal components of the diet;
- compared with the intake from other dietary sources, the veterinary medicinal use of potassium aspartate should not result in a significant increase in consumer intake of either component;

the Committee concludes that there is no need to establish an MRL for potassium aspartate and recommends its inclusion in Annex II of Council Regulation (EEC) 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Potassium aspartate	All food producing species	

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