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

EMEA/MRL/714/99-FINAL January 2000

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CONDURANGO CORTEX

SUMMARY REPORT

- 1. Condurango cortex is the dried bark of Marsdenia condurango Reichb. fil. The bark contains 1 to 3% of a mixture of pregnanic glycosides called condurangin. Condurangoglycosides A and C have been isolated from this mixture and their chemical structure determined. The structure of another aglycone marsdonin has also been determined. In addition condurangamin A and B have been isolated and found to be nicotinic acid esters of hydroxylated pregnane derivatives. Also present are inositol derivatives, flavonoids, cumaric derivatives, chlorogenic acid, caffeic acid, vanillin, a volatile oil, fat oil, resinous and pectic substances as well as vitamin B₁. The glycosides are more easily soluble in cold than in warm water.
- 2. In veterinary medicine *Condurango cortex* is contained at a concentration of 11% in a mixture of 5 powdered crude drugs, which is used for treatment of various gastric disorders in cattle, horses, swine, sheep and goats. The dose to cattle and horses corresponds to 2 g of *Condurango cortex* 3 times a day for treatment of gastric disorders and to 6 g twice a day for treatment of constipation. The doses for the smaller animals correspond to 1 g of *Condurango cortex* three times a day and 3 g twice a day, respectively.
 - In human medicine *Condurango cortex* is used as a bitter stomachic. The average daily dose is 2 to 4 g.
- 3. The bitter taste of *Condurango cortex* stimulates the appetite and favours salivation and secretion of gastric juices.
- 4. No information was provided on pharmacokinetics.
- 5. No reports were provided on acute toxicity or on repeated dose toxicity. Two glycosides (A and C) from the bark exhibited LD₅₀ values of 75 and 375 mg/kg of bodyweight, respectively (route of administration not given). Overdoses (no figures mentioned) may produce convulsions, ending in paralysis, vertigo and disturbed vision.
- 6. No information was provided on reproductive toxicity, teratogenicity, mutagenicity or cancerogenicity.
- 7. No information on immunotoxicity was provided.
- 8. No information on antimicrobial activity was provided.
- 9. No information on residues was provided.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for Veterinary Medicinal Products for the inclusion of substances in Annex II of Council Regulation (EEC) No 2377/90 and in particular that:

- *Condurango cortex* is expected to be used in a small number of individual animals only, for infrequent or non-regular treatments,
- the animals treated with *Condurango cortex* are unlikely to be sent for slaughter during or immediately after treatment,
- although there is no information on the toxicity of *Condurango cortex*, published LD₅₀ values for two isolated glycosides indicate a low toxicity,
- there are no reports on adverse effects from the use of *Condurango cortex* in human medicine;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for *Condurango cortex* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Condurango cortex, standardised extracts and preparations thereof	All food producing species	