



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

GINSENG

SUMMARY REPORT

1. *Ginseng* (synonyms: *Panax quinquefolius*, *Panax ginseng*, Five fingers) is a plant of the family *Araliaceae* widely distributed in the shady forests of East Asia. In veterinary homeopathy *Ginseng* is used as mother tincture prepared of the dried roots of *Ginseng* according to homeopathic pharmacopoeias, and dilutions thereof (white *Ginseng*). Constituents of the *Ginseng* roots are: triterpenoic saponins, and ginsenosides (up to 6%). The amount of ginsenosides in the root is dependent on the age of the plant and increases continuously every year. The major ginsenoside in the root is Rg₁. Further constituents are essential oils (0.05%), sesquiterpenes e.g. β -elemene, eremophilene, polyacetylene, panaxydol, panaxynol (falcarinol), panaxytriol (falcarintriol) phenolic derivatives, salicylate and vanillic acid, peptidoglycan, panaxan, and polysaccharides.
2. *Ginseng* is intended for use in all food-producing animals. The use follows the principles of homeopathic therapy where animals are diagnosed on basis of the individual pattern of clinical signs. The recommended maximum parenteral dose is 10 ml. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Ginseng is also used in human homeopathy as the mother tincture as well as in lower concentrations. The *Ginseng* root is traditionally used as a herbal drug in Chinese. In human phytotherapy a powder obtained from the dried roots of *Ginseng* is orally used as a remedy to increase physical and mental power, and to counteract cases of exhaustion. The recommended daily doses are 2 to 9 g.

The powdered roots are also used for preparations of tea and marmalades.

3. The acute toxicity of a *Ginseng*-extract (drug:extract 5:1) were investigated in minipigs and rats. Oral applications up to 4 g/kg induced no toxic effects. intraperitoneal LD₅₀ values of various pure ginsenosides on mice were: Rg₁: 1250 mg/kg; Rf: 1340 mg/kg; Re: 405 mg/kg; Rd: 324 mg/kg; Rc: 410 mg/kg; Rb₁: 1110 mg/kg; Rb₂: 305 mg/kg.
4. In a preliminary risk evaluation procedure by the CVMP considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Ginseng* and its individual constituents was considered as not giving rise to specific health concern. Further information made available and extensive search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Ginseng* alerting to specific health risks which may result from residues in food producing animals following the intended uses. Special emphasis was put on identification of suspicion pointing to genotoxicity or other potential of serious health effects of plant constituents.

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:

- *Ginseng* is used in a small number of individual animals and for non-regular treatments only,
- animals are unlikely to be sent for slaughter during or immediately after treatment,
- the substance and constituents thereof do not give rise to specific consumer health concern which may result from the use in veterinary homeopathy;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for any plant constituents of *Ginseng* following homeopathic uses and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 according to the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Ginseng</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only