



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

AESCULUS HIPPOCASTANUM (use in veterinary homeopathy)

SUMMARY REPORT

1. *Aesculus hippocastanum* (synonym: horse chestnut) is a plant of the family *Hippocastanaceae*. The fresh seeds (*Aesculus hippocastani semen*) are used for the preparation of medicinal and homeopathic products.

Major constituents of *Aesculus hippocastani semen* are a mixture of glycosidal triterpene saponins collectively referred to as 'aescine'; the major fraction with more than 40% is β -aescine, further tannins, phospholipids, sugars, starch (3 to 8%), flavonoids, oils, purine derivatives (adenine, adenosine, guanine, uric acid) and enzymes (laccase, esculinase, amylase). The saponins may be considered as the main pharmacologically active fraction with a content in fresh seeds of 7 to 15%.

The Committee for Veterinary Medicinal Products (CVMP) previously assessed *Hippocastani semen* in respect to its use in veterinary phytotherapy and recommended its inclusion in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Hippocastani semen</i>	All food producing species	For topical use only

2. This application relates to the use of the homeopathic mother tincture prepared by ethanolic extraction of fresh seeds of *Aesculus hippocastanum* (*Hippocastani semen*) according to homeopathic pharmacopoeias, and dilutions thereof in veterinary homeopathy. *Aesculus hippocastanum* 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 for large animals is 10 ml/animal. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.
3. The seeds of *Aesculus hippocastanum* are of moderate acute oral toxicity. Oral LD₅₀ values are reported for extracts of seeds (solvent and the weight relation crude drug/extract not given) in the following animal species: Guinea pig: 1120 mg/kg bw, mouse: 990 mg/kg bw, rat: 2150 mg/kg bw and rabbit: 1530 mg/kg bw. The triterpene saponins (aescin) contained therein are characterised by the following LD₅₀ values: mouse: 164 mg/kg bw (oral), 4.8 mg/kg bw (intravenous), 6.7 mg/kg bw (intraperitoneal), 38.5 mg/kg bw (subcutaneous); rat: 862 mg/kg bw (oral), 2.8 mg/kg bw (intravenous), 10.1 mg/kg bw (intraperitoneal), 150 mg/kg bw (subcutaneous).
4. The above Annex II recommendation for *Hippocastani semen* also covers topical use of the homeopathic veterinary medicinal products of *Aesculus hippocastani* in all concentrations including the mother tincture.

The use of *Aesculus hippocastanum* in veterinary homeopathy was further considered in a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products, considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000. Apart from the acute toxicity, further information made available and systematic search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Aesculus hippocastanum* and its constituents 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. It was concluded, that for all other routes of administration homeopathic dilutions of *Aesculus hippocastanum* resulting in concentrations in the veterinary medicinal product not exceeding 1 part per 10 may be used, as they can be considered as not giving rise to any specific consumer health concerns and provide a sufficient margin of safety.

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:

- topical use of *Hippocastani semen* has already been assessed by the CVMP and is recommended for inclusion in Annex II of Council Regulation (EEC) No 2377/90,
- *Aesculus hippocastanum* is used in a small number of individual animals for non-regular treatments,
- animals are unlikely to be sent for slaughter during or immediately after treatment,
- *Aesculus hippocastanum* and individual constituents thereof did not give rise to specific consumer health concern which may result from veterinary homeopathic uses;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for *Aesculus hippocastanum* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Aesculus hippocastanum</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per ten only