



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### HARPAGOPHYTUM PROCUMBENS

#### SUMMARY REPORT

1. *Harpagophytum procumbens* (synonym: Devils claw) belongs to the *Pedaliacea* family. The plant grows in desert areas of South and South-West Africa. The homeopathic mother tincture is prepared according to homeopathic pharmacopoeias by ethanolic extraction of the tuberous appendages of the roots of *Harpagophytum procumbens*.

*Harpagophytum procumbens* roots contain iridoid glycosides mainly harpagoside (0.5 to 1.6%), harpagide, procumbide (about 70 mg/kg), procumboside. Other constituents are flavones and flavonols (total of 0.018%) such as fisetine, kaempferol, kaempferide, luteolin, phenol ethyl derivatives such as the glycosides acteoside (about 1 g/kg drug) and isoacteoside (about 2 g/kg),  $\beta$ -(3',4'-dihydroxyphenyl)ethyl-O- $\alpha$ -L-rhamnopyranosyl-(1 $\rightarrow$ 3)- $\beta$ -D-glucopyranoside (100 mg/kg). Further components are gum resins, essential oils (0.03%), traces of harpagoquinone, up to 46% stachyose as reserve sugar (in dry matter).

2. In veterinary homeopathy the mother tincture of *Harpagophytum procumbens* is intended for oral or parenteral use in all food-producing species. 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. Corresponding doses in form of tablets, globules or drops are reported to contain lower amounts than the injectable form. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

The plant is also used in human homeopathy as the mother tincture as well as in lower concentrations. The drug prepared from dried tuberous secondary roots is also used in human phytotherapy for adjuvant treatment of degenerative rheumatism or painful arthrosis and tendinitis as well as for loss of appetite and dyspeptic complaints. The reported daily oral dose is 1.5 to 4.5 g drug.

3. The acute oral toxicity of *Harpagophytum procumbens* is low with a reported LD<sub>50</sub> of more than 13.5 g drug/kg bw in mice.
4. 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, the use of *Harpagophytum procumbens* and its individual constituents was considered as not giving rise to specific health concerns. Further information made available and systematic search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Harpagophytum procumbens* 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.

## 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:

- *Harpagophytum procumbens* 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,
- the plant and constituents thereof do not give rise to specific consumer health concerns which may result from 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 *Harpagophytum procumbens* following homeopathic use 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>Harpagophytum procumbens</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