

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CARLINAE RADIX

SUMMARY REPORT

1. *Carlinae radix* is a perennial Compositae, which grows on mountain pastures in Europe. Only the root is used as the crude drug for medicinal products. The roots of *Carlinae radix*, contain an essential oil obtained by distillation (1 to 2%), inulin (22%) and tannin. The main constituents of the essential oil are carlina oxide, an acetylenic substance derivated from furane (85 to 90%), 12 to 15% of a monocyclic sesquiterpene (carlinene), palmitic acid and traces of phenol.

Carlinae radix is used in veterinary medicinal products mainly in topical preparations together with other plant extracts or essential oils for antiseptic and healing purposes. A veterinary product containing 0.14% of the mother tincture (hydroethanolic solution) in combination with seven other essential oils and tinctures is used topically to promote the healing of wounds in cattle, horses, goats, sheep, pigs, rabbits and poultry. Wounds are liberally sprayed 3 to 4 times per day with the product until complete healing or applied by means of a wound dressing.

Preparations of *Carlinae radix* are used in traditional human medicine internally as diuretic, cholagogue and for treatment of cold and feverish illnesses. Externally they are used for ablution in the treatment of chronic dermatosis, acne and eczema. Internally the drug is applied as decoct or infusions in water (1.5 to 2.5%), as alcoholic tincture (1.5 to 3%) or extract in wine. The decoct is also used for external use.

In certain regions, people eat the receptacle of carlina's flowers.

2. Inulin is a mixture of oligo- and polysaccharides obtained from the tubers of different genera from the family Compositae, which by hydrolysis gives mainly fructose. It is rapidly removed from the circulation following intravenous administration but is not metabolised. Traces maybe found in the bile and may cross the placenta, but it is predominantly eliminated in the urine by glomerular filtration without secretion or reabsorption in the renal tubule. Inulin is used intravenously as a diagnostic agent to measure the glomerular filtration-rate. It is reported to have an inhibitory effect on the growth of transportable mouse tumour.

Tanninum was previously assessed by the Committee for Veterinary Medicinal Products and is included in Annex II of Council Regulation (EEC) No 2377/90 for all food producing species.

Carline oxide is reported to have anti-bacterial properties against Gram positive bacteria specially *Staphylococcus aureus* and fungi. In literature the essential oil of *Carlinae radix* is reported to be considered toxic due to its carline oxide content. No specific studies are available. However, it is also reported that the human medicinal products are not considered to be toxic as the concentration of carline oxide in these preparations is expected to be very low.

3. No information was available on the pharmacokinetic and toxicological profile of tinctures and extracts of *Carlinae radix*.

4. No information on residues of *Carlinae radix* and their depletion following treatment of food producing animals was provided. Considering however the knowledge on the main components of *Carlinae radix*, the low concentration at which of carlina oxide is expected to occur in the veterinary product even when hydro-alcoholic extraction of the drug is applied, and the fact that the drug is administered only topically, it is unlikely that consumers would be exposed to harmful levels of residues of *Carlinae radix* resulting from treatment of food-producing animals with the extract of this drug.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for Veterinary Medicinal Products for inclusion of substances into Annex II of Council Regulation (EEC) 2377/90 in particular that:

- *Carlinae radix* is used only topically in a small number of individual animals, for infrequent or non-regular treatments,
- treated animals are unlikely to be sent for slaughter during or immediately after treatment;
- the use of the extract of *Carlinae radix* in veterinary medical products is not likely to present a potential risk for the consumers of food derived from treated animals;

the Committee concludes that there is no need to establish an MRL for *Carlinae radix* 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
<i>Carlinae radix</i>	All food producing species	For topical use only