



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### EUPHRASIA OFFICINALIS

#### SUMMARY REPORT

1. *Euphrasia officinalis* (synonym: eyebright) is an aggregate of several *Euphrasia* subspecies, which are plants of the family *Scrophulariaceae*. *Euphrasia* is a frequent hemiparasite in grassland populations in North and Middle Eurasia, growing either unattached or attached to various host plants. The homeopathic mother tincture is prepared by ethanolic extraction of the entire flowering plant according to homeopathic pharmacopoeias.

Significant constituents of *Euphrasia officinalis* are iridoid glycosides. Aucubin, catapol, euphroside, eurostoside (10-p-cumaroylaucubin, 0.04%), geniposide, 7,8-dihydrogeniposid (adoxosid), ixoroside and mussaenoside in the dried herb of *Euphrasia rostkoviana* have been identified. Aucubin and ixoroside are found in *Euphrasia stricta*. The content of aucubin in the dried total plant of *Euphrasia stricta* was 0.94%. In above-ground parts of *Euphrasia rostkoviana* phenolic acids were found, such as caffeic acid (102 mg/kg), ferulic acid (traces), vanillic acid (6 mg/kg) and, following acid hydrolysis, chlorogenic acid (18.5 mg/kg), gallic acid (10.5 mg/kg), gentisinic acid, p-hydroxy phenylpyruvic acid, protocatechuic acid (together with gentisinic acid 48 mg/kg). Further constituents were phenylpropanoid glycosides, such as leucoseptoside A in herbs of *Euphrasia rostkoviana*, lignans (dehydro-coniferyl alcohol 4 $\beta$ -glycoside, 0.013% of the dry total plant) and mannit in the herbal parts. Additional constituents of *Euphrasia* are tertiary alkaloids, phytosterols ( $\beta$ -sitosterol, stigmasterol), flavones such as apigenin, chrysoeriol and luteolin, and galactosides as well as flavonolglycosides like quercetin-3-glycoside, quercetin-3-rutinoside and kaempferol-3-rutinoside.

2. In veterinary homeopathy the mother of *Euphrasia officinalis* and dilutions thereof are intended for parenteral 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.

*Euphrasia officinalis* is also used in human homeopathy as the mother tincture as well as in lower concentrations. In traditional medicine, *Euphrasia officinalis* preparations have been used topically for treatment of eye diseases and orally in form of teas (prepared from dried leaves, 2 to 4 g *Euphrasia herba*, several times a day) for treatment of stomach diseases, as well as oral powder (doses not reported).

3. 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 *Euphrasia officinalis* and its individual constituents was considered as not giving rise to specific health concerns. Further information made available and extensive search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Euphrasia officinalis* 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 any 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:

- *Euphrasia officinalis* is used only in a small number of individual animals for non-regular treatments,
- animals are unlikely to be sent for slaughter during or immediately after treatment,
- as normal and frequent constituent of grassland population, the plant is expected to be ingested by grazing food producing animals in small amounts on a regular basis via green forage, hay or silage,
- the plant and individual constituents thereof do 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 any plant constituents of *Euphrasia officinalis* following homeopathic uses 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>Euphrasia officinalis</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