



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

JECORIS OLEUM

SUMMARY REPORT

1. *Jecoris oleum* is the partially destearinated fixed oil expressed from fresh livers of cods and haddocks. It contains vitamin A (600 to 2500 IU/g), vitamin D (60 to 250 IU/g), vitamin E and ω_3 fatty acids as pharmacologically active principles. *Jecoris oleum* is contained in a concentration of 5% in one veterinary medical product in combination with 6 other active ingredients for topical use in all food producing species to promote wound healing.

In humans *Jecoris oleum* is used orally in the treatment of arteriosclerosis and for the prevention of infections and rickets (100 to 200 mg daily).

Vitamins A, D and E have previously been assessed by the Committee for Veterinary Medicinal Products (CVMP). Vitamins D and E have been included in Annex II of Council Regulation (EEC) No 2377/90 for all food producing species and vitamin A has also been recommended for inclusion in Annex II for all food producing species. Fatty acids are approved food additives under the European Parliament and Council Directive No 95/2/EC (E 570) and therefore are included in Annex II of Council Regulation (EEC) No 2377/90.

The ω_3 fatty acids decrease levels of very low density lipoproteins-cholesterine and triglyceride in blood as well the aggregation of platelets. In humans they are administered intravenously (100 to 200 mg/kg bw) or orally (4 to 10.5 g).

2. No information on the pharmacokinetics of *Jecoris oleum* is available. The ω_3 fatty acids are enzymatically converted in prostaglandine E_3 , F_3 and D_3 , prostacycline I_3 and thromboxane A_3 .
3. No data on the toxicity of *Jecoris oleum* were provided. However, taking into account that the pharmacologically active components have already been assessed separately such data were not considered necessary.
4. In humans the daily oral administration of 6 g *Jecoris oleum* has been reported to be without side effects.
5. In the assessment of vitamin A, an amount of 10 000 IU retinol equivalents were retained as the acceptable daily doses of vitamin A. This value corresponds to 4.0 to 16.6 g *Jecoris oleum*.
6. No residue studies with *Jecoris oleum* were provided. However, given the nature of the compound such data were not considered necessary.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for the inclusion of substances in Annex II of Council Regulation (EEC) No.2377/90 and in particular that:

- the pharmacologically active components of *Jecoris oleum* are vitamin A, vitamin D, vitamin E and ω_3 fatty acids,
- vitamins A and E are recommended for inclusion in Annex II, vitamin D and fatty acids are already included in Annex II,
- vitamins A, D and E and the ω_3 fatty acids are normal components of the human and animals diet,
- vitamins A, D and E and the ω_3 fatty acids are endogenously available substances,
- the ω_3 fatty acids are extensively metabolised in endogenous substances;

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