



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SOMATOLSALM

SUMMARY REPORT

1. Somatosalm is used as an osmoregulation factor in immature salmon for easing their adaptation from fresh water to sea water. One single dose of 10 µg somatosalm in 200 µl saline 0.9% is administered to anaesthetised fish, in the peritoneal cavity by an injection ahead of the pelvic fins.
2. Somatosalm is a recombinant protein of 21.590 daltons cloned from rainbow trout pituitaries. It belongs to the somatotropin family since its sequence is identical to that of rainbow trout somatotropin II.
3. Somatosalm is produced through a biotechnological process. The protein is expressed in a non-pathogenic recombinant microorganism, *Escherichia Coli* strain EGTP001, that fulfils the criteria defining the group I of the genetically modified microorganisms according to the European Community Directive 90/219/EEC.
4. The mechanisms of the osmoregulatory action of somatosalm are comparable to that of endogeneous somatotropins for controlling the ionic balance of the fish. Somatosalm binds to the fish somatotropin receptors and induces its osmoregulatory action through the mechanisms activated by endogeneous somatotropin.
5. After an intraperitoneal injection of the dose unit of 10 µg of somatosalm, the substance was progressively released in the blood stream. The maximum blood concentration of somatosalm (close to 1 µg/ml) was reached within 8 hours. Its concentration was back to endogeneous levels of somatotropin (<5 ng/ml) within 48 hours after IP administration. The half-lives of somatosalm were lower than 30 min whatever the season tested. At supraphysiological concentrations, the effects of somatosalm were transient and disappeared completely at 48 hours after treatment. Somatosalm was quickly catabolised.
6. On the basis of previous investigations on the biological activity of orally given somatotropins in mammals, somatosalm is believed as having no activity after oral administration.
7. No classical toxicity studies were provided.
8. The binding activity of Somatosalm to human receptors is extremely weak (8000 times weaker than human GH), 4 times weaker than ovine GH (equivalent to that of bovine GH).
9. Given to :
 - Σ the nature of the substance (protein),
 - Σ its half-life in fish (<30 min),
 - Σ its use pattern (single injection of 10 µg of active substance at 1-2 year before the slaughtering of fish for human consumption,this substance should be classified under Annex II of Council Regulation 2377/90.