



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

QUATRESIN

SUMMARY REPORT

1. Quatresin is myristyl-gamma-picolinium-chloride (synonyms: 4-methyl-1-tetradecyl-pyridinium-chloride; miripiriumchloride).
2. Quatresin is a quaternary ammonium compound, and a cationic surfactant which is used as a preservative in pharmaceutical products for animals and humans. It is used in some veterinary pharmaceutical formulations at a concentration of up to 0.025%.
3. In rats the LD₅₀ is 250 mg/kg bw after oral administration. After subcutaneous, intravenous and intraperitoneal administration the LD₅₀ is 200, 30 and 7.5 mg/kg bw respectively.

Quatresin has a history of use as a preservative in human medicinal products. In one case report two patients with a delayed hypersensitivity reaction to methylprednisolone showed also a concomitant delayed hypersensitivity to quatresin. No other information on toxicity of quatresin has been provided but chemically related quaternary compounds acting as a cationic surfactants with a pharmacological use as antiseptics (e.g. cetrimide, benzalkonium chloride, benzethonium chloride) show a relatively low toxicity.

4. No data on the kinetics of quatresin or residue depletion are available. However quaternary ammonium compounds are known to be poorly absorbed from the gastrointestinal tract after oral administration. The use of quatresin in food producing animals is unlikely to result in residue concentrations in food of animal origin which are toxicologically relevant for the safety of consumers.

Recommendations and conclusion :

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 :

- Σ the total dose administered to animals is low (less than 0.02 mg/kg bw),
- Σ quatresin belongs to the group of quaternary ammonium compounds which are known to be of low toxicity and are poorly absorbed from the gastrointestinal tract,
- Σ it will be used in a small number of individual animals,
- Σ quatresin has a long history of safe use in human medicinal products;

the Committee considers that there is no need to establish an MRL for quatresin 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
Quatresin	All food producing species	For use as a preservative only at concentrations of up to 0.5%