ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

EmpraSan Optima, 2.0% w/v, Concentrate for Teat Dip / Teat Spray Solution

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	EmpraSan Optima, 2.0% w/v, Concentrate for Teat Dip / Teat Spray Solution
Applicant	Kilco (International) Ltd
Active substance(s)	Iodine
ATC Vetcode	QG52A
Target species	Lactating dairy cattle
Indication for use	As an aid in the prevention of mastitis in lactating dairy cattle. After each milking the diluted product is applied directly to the teats by spraying or by teat dipping with a teat cup.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Lanodip 3:1 2.0% w/v, Concentrate for Teat Dip / Teat Spray Solution. The initial application for Lanodip 3:1 2.0% w/v, Concentrate for Teat Dip / Teat Spray Solution was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None