Veterinary Medicines Directorate

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

(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Proactive 0.15% w/w Teat Dip/Spray Solution

PuAR correct as of 22/06/2018 when RMS was transferred to IE.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0152/001/E/001
Name, strength and pharmaceutical form	Proactive 0.15% w/w Teat Dip/Spray Solution
Applicant	Delaval NV Industriepark – Drongen 10 9031 Gent Belgium
Active substance(s)	Iodine
ATC Vetcode	QD08AG03
Target species	Cattle
Indication for use	Teat disinfection to aid in the prevention of mastitis.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition	15 November 2001
Date product first authorised in the Reference Member State (MRP only)	05 July 2000
Concerned Member States for original procedure	Austria Germany Ireland The Netherlands
Concerned Member States for repeat use procedure	Belgium Czech Republic Greece

I. SCIENTIFIC OVERVIEW

The initial application for Proactive 0.15% w/w Teat Dip/Spray Solution was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available. This product was authorised via a Mutual Recognition procedure in Austria, Germany, Ireland and The Netherlands in 2002 and most recently through a second a round of Mutual Recognition in Belgium, Czech Republic and Greece.

When the product is used in accordance with the Summary of Product Characteristics, the risk benefit 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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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