IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Proactive 1.5 mg/g Teat Dip/Spray Solution

PRODUCT SUMMARY

EU Procedure Number	
Name, Strength, Pharmaceutical Form	Proactive 1.5 mg/g Teat Dip/spray solution
Active Substances(s)	Available iodine, ph. eur. (as iodine/sodium iodide/poloxamer complex 0.86)
Applicant	DeLaval NV Industriepark-Drongen 10 B-9031 Gent Belgium
Legal Basis of Application	Full application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Target Species	Cattle
Indication For Use	Teat disinfection to aid in the prevention of mastitis.
ATC Code	QD08AG03
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 (UK) 11 January 2002 (IE)
Concerned Member States for original procedure	Austria Germany Ireland The Netherlands
Concerned Member States for repeat use procedure	Belgium Czech Republic Greece UK added via RMS change

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.
The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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.