IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Nobilis Rismavac + CA126

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Nobilis Rismavac + CA126 Concentrate for solution for injection
Active substance(s)	Live Turkey Herpes virus strain FC126 Live Chicken Herpes virus strain CVI-988
Marketing Authorisation Holder	Intervet Ireland Ltd Magna Drive Magna Business Park Citywest Road Dublin 24
Marketing authorisation number	VPA No 10996/86/1
Legal basis of application	Complete application in accordance with Article 12.3(j) of Directive 2001/82/EC as amended.
Date of authorisation	6th August 2003
Target species	Chickens
Indication for use	For the active immunisation of 18-day embryonated eggs or day-old chickens to reduce mortality, clinical signs and lesions after infection with Marek's Disease virus.
ATCvet code	QI01AD03 Avian herpes virus vaccine (Mareks disease)

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 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 Nobilis Rismavac +CA126 was assessed before the requirement to produce a public assessment report. Details of the quality, safety and efficacy of Nobilis Rismavac +CA126 which led to the initial authorisation are therefore not included in the report.

Section VI of the report includes details of significant post-approval changes which have occurred since November 2005 which are considered important for the quality, safety and efficacy of the product.

II QUALITY ASPECTS

See section I.

III SAFETY ASSESSMENT

See section I.

IV CLINICAL ASSESSMENT (EFFICACY)

See section I.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the data submitted in the original application, the HPRA considers that Nobilis Rismavac +CA126 demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and was therefore granted a marketing authorisation.

VI 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 HPRA website.

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

Quality changes

Summary of change	**Approval date**
Change of ampoule size to 2 ml	6th August 2003
Change in fill volume from 1.0 ml to 1.8 ml. Addition of 4000 and 5000 dose presentations, Addition of diluent presentations containing 250 ml, 500 ml, 600 ml, 800 ml, 1000 ml and 1200 ml in polyethylene bags.	31st May 2006