ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bravoxin 10 Suspension for Injection for Cattle and Sheep

PuAR correct as of 21/02/2018 when RMS was transferred to DE. Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bravoxin 10 Suspension for Injection for Cattle and Sheep
Applicant	Intervet UK Ltd
Active substance(s)	*C. perfringens* type A (α) toxoid *C. perfringens* type B & C (β) toxoid *C. perfringens* type D (ε) toxoid *C. chauvoei* whole culture *C. novyi* toxoid *C. septicum* toxoid *C. tetani* toxoid *C. sordellii* toxoid *C. haemolyticum* toxoid
ATC Vetcode	QI02AB01 and QI04AB01
Target species	Sheep and Cattle from 2 weeks of age
Indication for use	For the active immunisation of sheep and cattle against disease associated with infections caused by *Clostridium perfringens* type A, *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *Clostridium chauvoei*, *Clostridium novyi* type B, *Clostridium septicum*, *Clostridium sordellii* and *Clostridium haemolyticum* and against tetanus caused by *Clostridium tetani*. For the passive immunisation of lambs and calves against infections caused by the above mentioned clostridial species (except *C. haemolyticum in sheep)*. The onset of immunity is two weeks after the primary course. Duration of active immunity: An anamnestic humoral immune response (immunological memory) to all components was demonstrated 12 months following the primary course of vaccination. As demonstrated by serology/persistent antibody titre only: Sheep *12 months against* C. perfringens *type A, B, C and D,* C. novyi *type B*, C. sordellii, C. tetani *< 6 months against* C. septicum, C. haemolyticum, C. chauvoei

	Cattle *12 months against* C. tetani *and* C. perfringens *type D* *< 12 months against* C. perfringens *type A, B and C* *< 6 months against* C. novyi type B, C. septicum, C. sordellii, C. haemolyticum, C. chauvoei Duration of passive immunity: As demonstrated by serology/persistent antibody titre only: For lambs At least 2 weeks for *C. septicum* and *C. chauvoei* At least 8 weeks for *C. perfringens* type B and *C. perfringens* type C At least 12 weeks for *C. perfringens* type A, C. *perfringens* type D, *C. novyi* type B, *C. tetani* and *C. sordellii* No passive immunity was observed for *C. haemolyticum*. For calves At least 2 weeks for *C. sordellii* and *C. haemolyticum* At least 8 weeks for *C. septicum* and *C. chauvoei* At least 12 weeks for C. *perfringens* type A, C. *perfringens* type B, C. *perfringens* type C, C. *perfringens* type D, *C. novyi* type B, and *C. tetani*

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 Covexin 10 Suspension for Injection for Sheep and Cattle. The initial application for Covexin 10 Suspension for Injection for Sheep and Cattle 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 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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