ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Norofas Solution for Injection

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Norofas Solution for Injection
Applicant	Norbrook Laboratories Limited
Active substance(s)	Ivermectin Closantel
ATC Vetcode	QP54AA51
Target species	Cattle
Indication for use	For the treatment of mixed trematode (fluke) and nematode or arthropod infestations due to gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice of cattle. Gastrointestinal roundworms *Ostertagia ostertagi* (including inhibited larval stages), *Ostertagia lyrata* (adult), *Haemonchus placei* (adult and immature), *Trichostrongylus axei* (adult and immature), *Trichostrongylus colubriformis* (adult and immature), *Cooperia oncophora* (adult and immature), *Cooperia punctata* (adult and immature), *Cooperia pectinata* (adult and immature), *Oesophagostomum radiatum* (adult and immature), *Nematodirus helvetianus* (adult), *Nematodirus spathiger* (adult), *Strongyloides papillosus* (adult), *Bunostomum phlebotomum* (adult and immature), *Toxocara vitulorum* (adult), *Trichuris* spp. Lungworms *Dictyocaulus viviparus* (adult and 4th stage larvae) Liver Fluke (trematodes) *Fasciola gigantica, Fasciola hepatica* Treatment of fluke at 12 weeks (mature) >99% efficacy. Treatment of fluke at 9 weeks (late immature) >90% efficacy Eyeworms (adult)

	Thelazia spp Cattle grubs (parasitic stages) *Hypoderma bovis, Hypoderma lineatum* Lice *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus* Mange Mites *Psoroptes ovis (*syn *P communis* var *bovis), Sarcoptes scabiei* var *bovis* Norofas Injection may also be used as an aid in the control of the biting louse *Damalinia bovis* and the mange mite *Chorioptes bovis*, but complete elimination may not occur. Persistent activity in cattle When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with Norofas Injection at the recommended dose rate of 200 g ivermectin per kg bodyweight and 5 mg closantel per kg bodyweight controls re-infection with: **Prolonged activity** *Dictyocaulus viviparus* Up to 28 days *Ostertagia ostertagi* Up to 21 days *Oesophagostomum radiatum* Up to 21 days *Cooperia* spp Up to 14 days *Trichostrongylus axei* Up to 14 days *Haemonchus placei* Up to 14 days

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 Closamectin Solution for Injection. The initial application for Closamectin Solution for Injection 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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