ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

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

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Granofen Wormer 888.8mg Granules for Dogs and Cats

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Granofen Wormer 888.8mg Granules for Dogs and Cats
Applicant	Virbac Ltd
Active substance(s)	Fenbendazole
ATC Vetcode	QP52AC13
Target species	Dogs and Cats
Indication for use	Granofen Wormer 888.8mg Granules for Dogs and Cats is indicated for the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of domestic dogs and cats. It also has an ovicidal effect and is indicated for the following: For the treatment of gastrointestinal nematodes and cestodes of domestic dogs and cats affected with *Ascarid* spp., *Ancylostoma* spp., *Uncinaria* spp., *Trichuris* spp., and *Taenia* spp. Also for the treatment of lungworm nematodes of domestic dogs affected with *Oslerus (Filaroides) osleri*, and domestic cats affected with *Aelurostrongylus abstrusus*. For the treatment of pregnant bitches to reduce pre-natal infections with *Toxocara canis* and the transfer of *Toxocara canis* and *Ancylostoma caninum* to their pups *via* the milk.

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 Granofen Wormer 222.2 mg Granules for Dogs and Cats. The initial application for Granofen Wormer 222.2 mg Granules for Dogs and Cats 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.

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