IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Abinex Forte 1 % w/v Pour On Solution

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Abinex Forte 1%w/v Pour On Solution
Active substance	Abamectin
Marketing Authorisation Holder	Bimeda Animal Health Limited, 2, 3 & 4 Airton Close Airton Road Tallaght Dublin 24 Ireland
Date of Authorisation	26/01/2001
Target species	Cattle (Beef and non-lactating dairy cattle)
Indication for use	A broad-spectrum endectocide of the avermectin family, effective against internal and external parasites sensitive to this family. For the treatment and control of the following mature and immature roundworms and lungworms in cattle: *Haemonchus* spp., *stertagia* spp., *Cooperia* spp., *Trichostrongylus* spp., *Oesophagostomum* spp., *Nematodirus* spp., *Trichuris* spp. (adults only) *Dictyocaulus* spp. Also for the treatment and control of sucking and biting lice (*Linognathus vituli* and *Damalinia bovis* respectively).
ATCvet code	QP54AA02

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 website.

I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to Section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and 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 or efficacy of the product.

Quality Changes

Summary of change	**Approval date**
Change in the immediate packaging of the finished product. Product is presented in 1 L and 2.5 L back pack flat bottomed HDPE containers provided with a cap on which normal pour-on equipment can be fitted.	10/04/2015
Reduction in shelf life	10/07/2018
Increase in an excipient	10/03/2021