

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

Dipen 100ml Suspension for Injection for cattle, sheep and pigs

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Dipen 100 ml Suspension for Injection for cattle, sheep and pigs
Active substances	Procaine benzylpenicillin Dihydrostreptomycin (as dihydrostreptomycin sulphate)
Marketing Authorisation Holder	Bimeda Animal Health Limited, 2, 3 & 4 Airton Close Airton Road Tallaght Dublin 24 Ireland
Legal basis of application	Informed consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of Authorisation	3 rd March 2006
Target species	Cattle, sheep and pigs.
Indication for use	For the treatment of infections caused by bacteria sensitive to penicillin and dihydrostreptomycin in Cattle, Sheep and Pigs.
ATCvet code	QJ01RA01

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 quality / safety / efficacy aspects of this product are identical to Pentomycin Suspension for injection (VPA 10990/005/001). The initial application for Pentomycin Suspension for injection was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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 Dipen 100 ml Suspension for Injection for cattle, sheep and pigs demonstrated adequate evidence of quality, safety and efficacy for the approved indication 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.

None.