IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Flunazine 50 mg/ml Solution for Injection for cattle, horses and pigs

PRODUCT SUMMARY

EU Procedure number	IE/V/0125/001/X/009
Name, strength and pharmaceutical form	Flunazine 50 mg/ml Solution for Injection for cattle, horses and pigs
Active substance(s)	Flunixin Meglumine
Applicant	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Airton Road Tallaght Dublin 24 Ireland
Legal basis of application	A generic application in accordance with Article13.1 of Directive 2001/82/EC as amended.
Date of completion of procedure	21st March 2002
Target species	Cattle, horses and pigs
Indication for use	**Cattle:** For the alleviation of acute inflammation associated with bronchopneumonia. **Horses:** For the alleviation of inflammation associated with musculoskeletal disorders, especially in acute to subchronic stages. It is also indicated for the alleviation of visceral pain associated with colic. **Pigs:** For use as an adjunctive therapy in the treatment of swine respiratory diseases.
ATCvet code	QM01AG90
Concerned Member States	BE, DE, ES, IT, LU, NL.

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 the 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's website.

I. SCIENTIFIC OVERVIEW

The initial application for Flunazine 50 mg/ml Solution for Injection for cattle and horses was assessed before there was a requirement to have a publicly available assessment report, therefore no details in this section are available. This report concerns an application by the marketing authorisation holder to include pigs as a target species.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This is a generic application according to Article 13.1, and bioequivalence with a reference product (Finadyne 50 mg/ml Solution for injection. VPA 10277/010/001 - Schering Plough) has been claimed in respect of the new target species pigs.

The applicant provided the results of a comparative analysis between the formulations of Flunazine 50 mg/ml Solution for Injection and the reference product Finadyne 50 mg/ml Solution. Based upon the data provided, it can be accepted that the formulations are sufficiently similar in terms of the active substance and excipients for the products to be considered the same. Consequently, the applicant's justification for the omission of bioequivalence studies was accepted.

It can be concluded that the safety aspects of this product following the inclusion of pigs as a target species will not be adversely affected and are considered to be identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users / the environment and consumers.

III.A Safety Testing

Pharmacological Studies
Toxicological Studies

No data provided. Given that an exemption from the requirement to demonstrate bioequivalence with the reference product has been adequately justified, the omission of safety tests was accepted.

User Safety

No specific user safety assessment was provided. Safety of the formulation for the user was already assessed and accepted following the initial mutual recognition procedure. It can be accepted that the addition of pigs as a target species will not significantly alter the safety profile of the product in terms of user safety.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that the product will only be used to treat a small number of animals in a herd and therefore the environmental risk assessment may end in phase I. No additional warnings in respect of the environment were deemed necessary following the inclusion of pigs as a target species.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted. Normally, for a generic product intended to be administered intramuscularly, the results of injection site residue depletion studies are required. However, in this instance, the applicant provided acceptable data to demonstrate that the qualitative and quantitative composition of Flunazine 50 mg/ml solution for injection (in terms of active substance and excipients) is essentially similar to that of the reference product (Finadyne 50 mg/ml solution for injection). The omission of studies conducted in pigs administered Flunazine 50 mg/ml solution for injection to investigate the rate of residue depletion from the injection site could therefore be accepted.

MRLs

Flunixin is included in table 1 of Commission Regulation (EU) No. 37/2010 with the following information recorded for pigs. The marker substance is Flunixin.

Pharmacologically active substance	Marker residue	Animal species	MRL (microgram/kg)	Target tissue	Other provisions	Therapeutic classification
Flunixin	Flunixin	Porcine	50	Muscle	None	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents
			10	Skin & fat		
			200	Liver		
			30	Kidney		

Withdrawal Periods

Based upon the data provided, it can be accepted that the formulations are sufficiently similar in terms of the active substance and excipients for the products to be considered the same. The withdrawal period for porcine meat and offal of 24 days established for the reference product is considered to be equally applicable for Flunazine 50 mg/ml. Further, the applicant proposed the same restriction on the maximum injection volume (5 ml) that may be administered intramuscularly at each injection site as approved for the reference product.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

This is a generic application according to Article 13, and bioequivalence with a reference product (Finadyne 50 mg/ml Solution for injection. VPA 10277/010/001 - Schering Plough) has been claimed in respect of the target species pigs.

The applicant provided the results of a comparative analysis between the formulations of Flunazine 50 mg/ml Solution for Injection and the reference product Finadyne 50 mg/ml Solution. Based upon the data provided, it can be accepted that the formulations are sufficiently similar in terms of the active substance and excipients for the products to be considered the same. Consequently, the applicant's justification for the omission of bioequivalence studies was accepted and efficacy studies were not required. The efficacy claims for this product in pigs are equivalent to those of the reference product.

Tolerance in the Target Species of Animals

Normally, for generic veterinary medicinal products intended to be administered by the intramuscular route, evidence to demonstrate target animal tolerance at the administration site is required.
Based upon the data provided, it can be accepted that the formulations are sufficiently similar in terms of the active substance and excipients for the products to be considered the same. The absence of specific target animal tolerance studies conducted in pigs was therefore accepted as it is not expected that there will be any difference in tolerance in pigs administered Flunazine 50 mg/ml and the reference product Finadyne 50 mg/ml.

IV.B Clinical Studies

Laboratory Trials
Field Trials

No data provided. This is a generic application according to Article 13, and bioequivalence with a reference product (Finadyne 50 mg/ml Solution for injection. VPA 10277/010/001 - Schering Plough) has been claimed in respect of the target species pigs.

The applicant provided the results of a comparative analysis between the formulations of Flunazine 50 mg/ml Solution for Injection and the reference product Finadyne 50 mg/ml Solution. Based upon the data provided, it can be accepted that the formulations are sufficiently similar in terms of the active substance and excipients for the products to be considered the same. Consequently, the applicant's justification for the omission of bioequivalence studies was accepted.

It can be concluded that the efficacy claims for the reference product are equally applicable for Flunazine 50 mg/ml Solution for Injection.

V. 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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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.

Changes:

Safety/Efficacy Changes

Summary of change **(Application number)**	**Approval date**
Addition of target species - pigs (IE/V/0125/001/X/009)	26th October 2011