IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Dexafast 2 mg/ml solution for injection for horses, cattle, goats, pigs, dogs and cats

PRODUCT SUMMARY

EU Procedure number	IE/V/0390/001/DC
Name, strength and pharmaceutical form	Dexafast 2 mg/ml solution for injection for horses, cattle, goats, pigs, dogs and cats
Active substance(s)	Dexamethasone
Applicant	Industrial Veterinaria S.A., Esmeralda 19, Esplugues De Llobregat, Barcelona, 08950, Spain
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of Authorisation	N/A
Target species	Horses, Cattle, Goats, Pigs, Dogs and Cats
Indication for use	Horses, cattle, pigs, dogs and cats: Treatment of inflammatory or allergic conditions. Cattle: Induction of parturition. Treatment of primary ketosis (acetonaemia). Goats: Treatment of primary ketosis (acetonaemia). Horses: Treatment of arthritis, bursitis or tenosynovitis
ATCvet code	QH02AB02
Concerned Member States	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, HR, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI)

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 product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species.
The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 2 mg/ml of the active substance dexamethasone as the sodium phosphate salt and the excipients benzyl alcohol, sodium chloride, sodium citrate dihydrate, sodium hydroxide, citric acid and water for injections.
The container/closure system is a colourless, Type I glass vials containing 20 ml, 50 ml or 100 ml, closed with halogenobutyl rubber stoppers and sealed with aluminium caps
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.
Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is dexamethasone as the sodium phosphate salt an established an established substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.
The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies
Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on Intermediate Products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.
Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application was for Dexafast 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats containing dexamethasone sodium phosphate as active substance and has been submitted using the decentralised procedure in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC (application for a generic veterinary medicinal product).
The reference veterinary medicinal product is Dexadreson 2 mg/ml Solution for Injection (VPA 10996/027/001 - Intervet Ireland Ltd.) which was first granted a marketing authorisation in the RMS on 01/10/1989. The reference product has been authorised within the Community for not less than 10 years based upon a full dossier and can be accepted as being a suitable reference product.

The omission of *in-vivo* bioequivalence data was accepted based upon satisfactory demonstration of essential similarity between the generic and reference product formulations.
As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been accepted, results of safety tests are not required.
The safety aspects of this product are considered to be the same as for the reference product.
Warnings and precautions as listed on the product literature are in line with those of the reference product and other similar products that have been recently authorised and are considered adequate to ensure safety of the product for users and the environment.

III.A Safety Testing

Pharmacological Studies
As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no pharmacological study data was required.
The pharmacokinetic and pharmacodynamic characteristics of the product are not expected to differ to those of the reference product.

Toxicological Studies
As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no toxicological study data was required.
The toxicological profile of the product is not expected to differ to that of the reference product.

User Safety
A user safety assessment was provided. Based upon satisfactory demonstration of essential similarity between the generic and reference product formulations, it was accepted that no difference in terms of safety for the user is anticipated between generic and reference products. Further, the product is intended to be administered to the same target species, using the same route of administration at the same dose rate as already approved for the reference product.
Warnings and precautions as listed on the product literature are considered adequate to ensure safety to users of the product.
It was concluded that the product will not present an unacceptable risk for the user when handled, used, stored and disposed of in accordance with the recommendations included in the SPC.

Environmental Risk Assessment
An environmental risk assessment was provided

Phase I
The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the product meets the guideline criteria for being considered a type of product that will be used to treat a small number of animals.
It was concluded that the product will not present an unacceptable risk for the environment when handled, used, stored and disposed of in accordance with the recommendations included in the SPC.

III.B Residues Documentation
As the candidate formulation was accepted as being the same as that of the reference product, studies investigating the depletion of residues from the injection site were not required as no difference in depletion of residues from the injection site is expected.
Consequently, the same withdrawal periods approved for the reference product in the RMS could be applied to the candidate formulation.
It was concluded that use of the product will not present an unacceptable risk to the consumer of animals that have been administered the product in accordance with the recommendations included in the proposed SPC and that the proposed withdrawal periods are adequate to ensure consumer safety.

IV. CLINICAL ASSESSMENT

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no target animal tolerance study data was required.
Tolerance in the target animal is not expected to differ between the generic and reference products. Suitable warnings have been included in the SPC to ensure the safe use of the product in the target species.
The product literature accurately reflects the type and incidence of adverse effects which might be expected following use of the product.

Field Trials

As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no field trials were required.

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 benefit/risk 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:

None.