College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DEXAMECINE 2 mg/ml solution for injection

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0268/001
Name, strength and pharmaceutical form	DEXAMECINE 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats
Applicant	VET-AGRO TRADING Sp. z o.o. Mełgiewska 18, 20-234 Lublin, Poland.
Active substance(s)	Dexamethasone
ATC Vetcode	QH02AB02
Target species	Cattle, horses, pigs, dogs and cats
Indication for use	Horses Treatment of inflammation and allergic reactions. Treatment of arthritis, bursitis or tenosynovitis. Cattle Treatment of inflammation and allergic reactions. Induction of parturition. Treatment of primary ketosis (acetonaemia). Pigs Treatment of inflammation and allergic reactions. Dogs and cats Treatment of inflammation and allergic reactions.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13.2. of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	31.01.2018
Date product first authorised in the Reference Member State (MRP only)	N.A.
Concerned Member States for original procedure	DE, HU, IT, NL, UK

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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 slight reactions observed are indicated in the SPC.
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 risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 2 mg of dexamethasone as dexamethasone sodium phosphate per ml and the excipients benzyl alcohol, sodium chloride, sodium citrate, sodium hydroxide, citric acid (monohydrate) and water for injections.

The container/closure consists of 100 ml amber co-ex plastic (PP) vials closed with bromobutyl rubber stoppers and aluminium caps. Vials are individually packed in cardboard boxes.

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.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is dexamethasone sodium phosphate, an established active 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 have been provided.

Certificate of suitability issued by the EDQM has been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

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 have 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 have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

The claim of 28 days stability after first opening is based on the demonstration of stability for a batch broached and stored 28 days in condition stated in SPC.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological, pharmacological, safety of residues tests are not required.

III.A Safety Testing

Toxicological Studies

As this is a generic application submitted according to Article 13(1) of Directive 2001/82/EC as amended and bioequivalence between generic product Dexamecine and reference product Dexadreson was established, results of toxicological studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I because the evaluation was stopped at point 3 for dogs and cats (non-food animals) and then at point 4 for horses (minor species referring to cattle as major species) and at point 5 for cattle and pigs (major species). The product is injectable corticosteroid to be used as a single injection for treatment of a small number of animals. No more than individual or a few animals in a flock or herd will be treated and therefore Environmental Risk Assessment ends at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

Residue Studies

The applicant has submitted the generic application in accordance with Article 13(1) of Directive 2001/82/EC, as amended.

No residue depletion studies were required at this case.

MRLs

Dexamethasone is an allowed substance as described in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Dexamethasone	Dexamethasone	Bovine, caprine, porcine, *Equidae*	0.75 µg/kg 2 µg/kg 0.75 µg/kg	muscle liver kidney	NO ENTRY	Corticoides/ Glucocorticoides
		Bovine, caprine	0.3 µg/kg	milk		

Withdrawal Periods

Based on information above, the following withdrawal periods were approved:

Cattle:
Meat and offal: 8 days
Milk: 72 hours **Pigs:**
Meat: 2 days **Horses:**

Meat and offal: 8 days
Not authorized for use in horses producing milk for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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.

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 Heads of Veterinary Medicines Agencies website (www.HMA.eu).

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.

Summary of change (Application number)	**Section updated in Module 3**	**Approval date**
RMS change from CZ to NL	N/A	25 May 2018