Institute for State Control of Veterinary Biologicals and Medicines
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(Reference Member State - CZ)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dexrapid 2 mg/ml solution for injection

(AT, BE, BG, CZ, DE, EL, ES, FR, HU, IE, LT, NL, PL, PT, RO, SI, SK)

Dexrapid vet. 2 mg/ml solution for injection

(DK, FI)

Dexapid vet. 2 mg/ml solution for injection

(SE)

MODULE 1

PRODUCT SUMMARY

EU Procedure number	CZ/V/167/01/DC
Name, strength and pharmaceutical form	Dexrapid 2 mg/ml solution for injection (AT, BE, BG, CZ, DE, EL, ES, FR, HU, IE, LT, NL, PL, PT, RO, SI, SK) Dexrapid vet. 2 mg/ml solution for injection (DK, FI) Dexapid vet. 2 mg/ml solution for injection (SE)
Applicant	Richter Pharma AG, Feldgasse 19 A-4600 Wels, Austria
Active substance(s)	Dexamethasone
ATC vet code	QH02AB02
Target species	Horses, cattle, pigs, dogs and cats
Indication for use	Horses, cattle, pigs, dogs and cats: Treatment of inflammatory or allergic conditions. Horses: Treatment of arthritis, bursitis or tenosynovitis. Cattle Induction of parturition. Treatment of primary ketosis (acetonemia). Dogs and cats Short-term treatment of shock.

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 – Art. 13.2. of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23/09/2020
Date product first authorised in the Reference Member State (MRP only)	NA
Concerned Member States for original procedure	AT, BE, BG, DE, DK, EL, ES, FI, FR, HU, IE, LT, NL, PL, PT, RO, SE, SI, SK

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 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 (in a form of dexamethasone sodium phosphate) per 1 ml and benzyl alcohol, sodium chloride, sodium citrate, sodium hydroxide, citric acid monohydrate and water for injections as excipients.

The container/closure system consists of 100 ml colourless glass vials (type II) closed with bromobutyl rubber stopper and aluminium flip-off cap.

The choice of the formulation is sufficiently justified.

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 on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance, dexamethasone, is 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.

Scientific data has been provided as appropriate and 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 (pharmaceuticals)

The tests performed during production are described and the results conforming to the specification are provided.

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 in-use shelf-life of the product is supported by relevant data.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

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

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the assessment can stop at question no. 3 of the decision tree for dogs and cats (non-food animals) and for cattle, pigs and horses the assessment can stop at question no. 5 of the decision tree as the veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

The application for the product is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, as a generic of the authorised product Dexadreson 2 mg/ml solution for injection (Intervet International B.V.), which has been authorised since 1995 in the Czech Republic. Exemption from bioequivalence is claimed on the basis of the product being identical to the reference product.

Residue Studies

No residue depletion studies were conducted.

MRLs

Dexamethasone is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010. The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
		Bovine, caprine	0.3 µg/kg	milk		

Withdrawal Periods

Based on the data provided above the following withdrawal periods are established:

Withdrawal period(s):
Horses
Meat and offal: 8 days
Not authorised for use in mares producing milk for human consumption.

Cattle
Meat and offal: 8 days
Milk: 72 hours

Pigs
Meat and offal: 2 days

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

None