AGENCE NATIONALE DU

MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DEXAMETHASONE VMD 2 MG/ML, Solution for injection for cattle, pigs, goats, horses, dogs and cats

01/09/2025

PRODUCT SUMMARY

EU procedure number	FR/V/0505/001/DC
Name, strength and pharmaceutical form	DEXAMETHASONE VMD 2 MG/ML, Solution for injection for cattle, pigs, goats, horses, dogs and cats
Applicant	VMD HOGE MAUW 900 2370 ARENDONK BELGIUM
Active substance(s)	Dexamethasone (as dexamethasone sodium phosphate)
ATC vetcode	QH02AB02
Target species	Horses, cattle, goats, pigs, dogs and cats.
Indication for use	<u>Horses, cattle, goats, pigs, dogs and cats:</u> Treatment of inflammation and allergic reactions. <u>Horses:</u> Treatment of arthritis, bursitis or tenosynovitis. <u>Cattle:</u> Treatment of primary ketosis (acetonemia). Induction of parturition. <u>Goats:</u> Treatment of primary ketosis (acetonemia).

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6.
Reference product (RP)	DEXADRESON
Marketing authorisation holder	INTERVET
Marketing authorisation number EU procedure number	01637
Date of authorisation	30/06/1992
Concerned Member States for original procedure	BE, BG, EE, HU, LT, LU, LV, NL, PL, RO
Concerned Member States for subsequent recognition procedure	/
Withdrawn CMS during original <mutual recognition> <decentralised><subsequent recognition> procedure	/

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains the active substance Dexamethasone (as dexamethasone sodium phosphate) at a concentration of 2.0 mg/mL and the following excipients: benzyl alcohol, sodium chloride, sodium citrate dihydrate, sodium hydroxide, citric acid and water for injections.

The container/closure system is as described on the SPC. The particulars of the containers and performed controls are provided and conform to the regulation.

The choice of the formulation and presence of preservative are justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

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

C. Production and control of starting materials

The active substance is Dexamethasone (as dexamethasone sodium phosphate), an established active substance described in the European Pharmacopeia. 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.

Certificates of suitability issued by the EDQM have been provided 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 tests carried out on isolated intermediates during the manufacturing process

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 VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability tests

A re-test period for the active substance is set in one of the certificates of suitability issued by EDQM. Otherwise, stability data on the active substance have 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 VMP throughout its shelf life when stored under the approved conditions.

An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological Studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with the reference product has been demonstrated, results of pharmacological tests are not required.

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of this product are identical to the reference product.

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.
If used as recommended, the product will have a negligible impact on the environment.

B. Residues documentation

Residue tests

No depletion data was provided.

Maximum Residue Limits

The active substance, dexamethasone, is included in table 1 of the annex of the Commission regulation (EU) No. 37/2010, as follows:

Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification	Regulation
Dexamethasone	Bovine, caprine, porcine, Equidae	0.75 µg/kg 2.00 µg/kg 0.75 µg/kg	Muscle Liver Kidney	No entry	Cortocoïdes/ Glucocorticoïdes	37/2010 of 22.12.2009
	Bovine, caprine	0.30 µg/kg	Milk			

The MRL status of excipients of the product is indicated in the following table.

Excipient	MRL status
Benzyl alcohol	Table 1, all food species, no MRL required
Sodium chloride	Table 1, all food species, no MRL required
Sodium citrate dihydrate	*
Citric acid	*
Sodium hydroxyde	*
Water for injection	Out of scope list

* Covered with food additives (substance with a valid E number approved as additives in foodstuffs for human consumption)

The composition of the product is acceptable according to the European Regulation (EC) 470/2009.

Withdrawal Periods

It is a generic application submitted to Article 18 of Regulation (EC) 2019/6. The withdrawal periods are the same as those for the reference product:

Cattle and goats:
Meat and offal: 8 days
Milk: 72 hours

Pigs:
Meat and offal: 2 days following intramuscular administration
Meat and offal: 6 days following intravenous administration

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

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

A. Pre-Clinical Studies

Pharmacology

It is a generic application submitted according to Article 18 of Regulation (EC) 2019. The cited reference product is DEXADRESON (Intervet).

Pharmaceutical form
The test and the reference products have the same pharmaceutical form: solution for injection.

Active substance qualitative and quantitative composition
The test and reference products have the same qualitative and quantitative composition in active substance: 2.0 mg of dexamethasone per mL.

Bioequivalence studies
No bioequivalence study was performed.
In line with the current bioequivalence guideline (EMA/CVMP/016/00 – Rev.4), an exemption from bioequivalence study is claimed based on the similar formulations of the two products.

Tolerance in the target species of animals

The applicant has not provided tolerance study, which is acceptable because the safety profiles of the excipients are well established and the tested product and the reference product have similar formulations.
The tolerance aspects of this product are identical to the reference product.
Based on the conclusion made for the reference product, the product literature accurately reflects the type and incidence of adverse effects, which might be expected.

Dose determination and confirmation

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been demonstrated, no dose determination or dose confirmation studies were provided.

B. Clinical trials

As this is a generic application according to Article 18 of Regulation (EC) 2019/6, 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.

5. 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.