

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

OXITOVET 10 IU/ml solution for injection

OXITOVET 10 IU/ml solution for injection	ES/V/0424/001/DC
SUPER'S DIANA S.L.	DCP
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PRODUCT SUMMARY

EU procedure number	ES/V/0424/001/DC
Name, strength and pharmaceutical form	OXITOVET 10 IU/ml solution for injection
Applicant	Super's Diana S.L. Carretera C 17 Km 17 Parets Del Valles – 08150 - Spain
Active substance(s)	Oxytocin
ATC vetcode	QH01BB02
Target species	Cattle (cow) Pig (sow) Horse (mare)
Indication for use	Induction to parturition. Uterine inertia or atony. Uterus involution after caesarean section and reduction of haemorrhages. Expulsion of afterbirth and exudates after parturition. Milk ejection after parturition. Agalactia in sows. Induction of the expulsion of exudates in cases of chronic pyometritis and endometritis Adjuvant treatment to antibiotic therapy of acute and chronic mastitis, to induce the expulsion of residues and facilitating drainage

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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).

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SUMMARY OF ASSESSMENT

Legal basis of original application*	DCP application in accordance with Article 18 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018
Reference product (RP)	OXITOCINA DIANA 10 UI/ml solution for injection
Marketing authorisation holder	SUPER'S DIANA S.L
MS where the RP is or has been authorised <i>[if not authorised in the RMS]</i>	N/A
Marketing authorisation number	669 ESP
EU procedure number	
Date of authorisation	08-03-1993
Date of completion of the original decentralised procedure	12/12/2023
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	CZ, PL, RO, SI, SK
Concerned Member States for subsequent recognition procedure	N/A

*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

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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.

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

2.A. Product description

The VMP contains 10.0 IU/ml of oxytocin and the excipients sodium chloride, chlorobutanol hemihydrate, ethanol (96 per cent), acetic acid glacial and water for injections

The container/closure system is a 100 ml or 250 ml polypropylene vial closed with a bromobutyl rubber stopper and an aluminium cap.

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

2.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.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

2.C. Production and control of starting materials

The active substance is oxytocin, 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.

2.D. <Control tests carried out on isolated intermediates during the manufacturing process>

2.D. <Control tests during the manufacturing process>

2.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.

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2.F. Stability tests

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.

2.F. Batch-to-batch consistency

Data from 4 representative batches of the VMP have been provided in order to ensure that quality is consistent from batch to batch and to demonstrate conformity with specifications.

2.G. Other information

2.G. Stability tests

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.

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3. SAFETY DOCUMENTATION (safety and residues tests)

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

The safety and residue aspects of this VMP are identical to the reference VMP.

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

3.A. Safety tests

Pharmacological studies

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

Toxicological studies

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

User safety

Given that the candidate formulation can be accepted as being bioequivalent to the reference product, no formulation specific risks are anticipated for the user when compared with the reference product.

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

Environmental Risk Assessment

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

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will be used to treat a small number of animals in a flock or herd.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted because bioequivalence with the reference product has been demonstrated

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Maximum Residue Limits

Oxytocin is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provision	Therapeutic Classification
Oxytocin	NOT APPLICABLE	All mammalian food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Oxytocin

Withdrawal Periods

Based on the justifications provided, the same withdrawal periods as approved for the reference veterinary medicinal product can be accepted for this generic veterinary medicinal product; A withdrawal period of zero days for meat in cows, sows and mares and zero hours for milk are justified.

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4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

The VMP complies with the exemption 7.1.d) of the "Guidelines for the conduct of bioequivalence studies for veterinary medicinal products" (EMA/CVMP/016/00-Rev.4). The formulations are identical and have the same physicochemical properties.

These conditions are met by the VMP and therefore the exemption of bioequivalence is demonstrated.

4.A. Pre-Clinical Studies

No pre-clinical studies were performed.

4.B. Clinical trials

No clinical trials were performed.

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5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

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POST-AUTHORISATION PROCEDURES

None.