IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Oxytobel 10 IU/ml solution for injection for horses, cattle, pigs, sheep, goats, dogs and cats.

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0313/001/DC
Name, strength and pharmaceutical form	Oxytobel 10 IU/ml solution for injection for horses, cattle, pigs, sheep, goats, dogs and cats.
Active substance	Oxytocin
Marketing Authorisation Holder	Bela-Pharm GmbH & Co. KG Lohner Straße 19 D-49377 Vechta Germany
Legal basis of application	Generic application in accordance with Article 13.1 of Directive 2001/82/ES as amended
Date of Authorisation	20th November 2013
Target Species	Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats
Indication for use	In the mare, cow, sow, ewe, goat, bitch and cat the product is indicated for: · Obstetric use (stimulation of uterine contraction to facilitate parturition in the presence of a fully dilated cervix, promotion of involution of the post partum uterus, aid in the control of post partum haemorrhage). · Promotion of milk let-down in cases of agalactia.
ATC Vetcode	QH01BB02
Concerned Member States	DK, IS, NO, UK

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.

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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 16.6 µg/ml oxytocin and the excipients chlorobutanol hemihydrate, acetic acid (glacial), ethanol 96% and water for injections.

The packaging materials are amber glass vials with bromobutyl rubber stoppers and aluminium overseals which are standard for this dosage form.

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 in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is oxytocin 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 have been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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 have been provided demonstrating compliance with the specification.

F. Stability

Stability of the active substance has been demonstrated in accordance with applicable European guidelines.

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. ***G. Other Information***

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This is a generic application according to Article 13.1. The reference product is Oxytocin aniMedica 10 IU/ml solution for injection. Acceptable justification for omitting in-vivo comparative bioavailability study data was provided, based upon the essential similarity between candidate and reference product formulations. Consequently, it was accepted that bioequivalence of the candidate formulation with the reference formulation has been suitably demonstrated.

The safety and residue aspects of this product are considered identical to 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 recently authorised via European procedures and are considered adequate to ensure safety of the product to users, the environment and consumers.

III.A Safety Testing

Pharmacological Studies

This application was submitted in accordance with Article 13.1 (a generic application). Given that bioequivalence with a reference product has been demonstrated, no pharmacological studies were conducted.

Toxicological Studies

This application was submitted in accordance with Article 13.1 (a generic application). Given that bioequivalence with a reference product has been demonstrated, no toxicological studies were conducted.

User Safety

A user safety assessment was provided in compliance with the relevant guideline. The candidate formulation includes oxytocin at the same concentration as the reference product and is to be administered at the same dose rates as the reference product. Consequently, no increased exposure to the user is anticipated.

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

Similarly to the reference product, pregnant or lactating women should avoid handling the product, as exposure may result

in smooth muscle (e.g. uterine) contraction.

Warnings and precautions as listed on the product literature are in line with those approved for the reference product and are considered adequate to ensure safety to users of the product.

Environmental Risk Assessment

A first phase environmental risk assessment was provided in compliance with the relevant guideline.

The product is for parenteral administration to individual animals for obstetric purposes and for the treatment of agalactia. As such, the product will be used in individual animals.

The first phase environmental impact assessment showed that no further assessment is required. The assessment concluded that no special warnings regarding the environment are required.

Warnings and precautions as listed on the product literature are in line with those approved for the reference product and are considered adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted. Based upon the essential similarity between candidate and reference formulations, it could be concluded that any minor differences between formulations will not impact upon the rate or extent of residue depletion from injection sites. On that basis, the omission of residue depletion studies was accepted.

MRLs

Oxytocin is listed in Table 1 of Commission Regulation (EU) No. 37/2010 as indicated below.

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissue	Other provisions
Oxytocin	NOT APPLICABLE	All mammalian food producing species	No MRL required	NOT APPLICABLE	No entry

Withdrawal Periods

Based on the justifications provided, the same withdrawal periods as approved for the reference product can be accepted for this generic product; namely zero days for meat and offal and zero hours for milk.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to Article 13.1 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.

Tolerance in the Target Species of Animals

No target animal tolerance studies were conducted. Based upon the essential similarity between candidate and reference formulations, it could be concluded that any minor differences between formulations will not impact upon target animal tolerance.

The candidate formulation will be administered to the same target species, using the same routes of administration at the same dose rates. On that basis, the omission of target animal tolerance studies was accepted.

IV.B Clinical Studies

As this is a generic application according to Article 13.1 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 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.

Quality Changes

Summary of change	Approval date
Change in the (invented) name of the medicinal product: name change IE/V/0313/001/IB/001	08th May 2014