DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

BIOCOM P Vet, suspension for injection for mink

Created: December 2019
## PRODUCT SUMMARY

<table>
<thead>
<tr>
<th>EU Procedure number</th>
<th>NL/V/0227/001/DC</th>
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<tbody>
<tr>
<td>Name, strength and pharmaceutical form</td>
<td>BIOCOM P Vet, suspension for injection for mink</td>
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<tr>
<td>Applicant</td>
<td>United Vaccines Holding B.V. Molenweg 7 6612 AE Nederasselt The Netherlands</td>
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<tr>
<td>Active substance(s)</td>
<td>Inactivated Mink Enteritis Virus types 1 and 2 <em>Clostridium botulinum</em> type C toxoid Inactivated <em>Pseudomonas aeruginosa</em> serotypes 5, 6, and 7-8</td>
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<tr>
<td>ATC Vetcode</td>
<td>QI20CL01</td>
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<tr>
<td>Target species</td>
<td>Mink</td>
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<tr>
<td>Indication for use</td>
<td>For the active immunization of mink from an age of 6 weeks to reduce mortality and clinical symptoms caused by Mink Enteritis Virus Types 1 and 2, <em>Clostridium botulinum</em> Type C toxin, and <em>Pseudomonas aeruginosa</em> Serotypes 5, 6, and 7-8 (in accordance with the International Antigenic Typing Scheme (IATS)).</td>
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</table>
The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).
PUBLIC ASSSESSMENT REPORT

Legal basis of original application | Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
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Date of completion of the original decentralised procedure | 20 September 2017
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Date product first authorised in the Reference Member State (MRP only) | N/A
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Concerned Member States for original procedure | DK, EL, ES, IT, LT, LV, NO, PL, RO, SE
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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 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.

Biocom P Vet is a generic product. The reference product is BIOCOM-P, suspensie voor injectie voor nertsen, first authorized in the Netherlands on 27 June 2000 (REG NL 6385) by Coöperatieve Federatie van Edelpelsdierenhouders (CFE). The initial application for BIOCOM-P, suspensie voor injectie voor nertsen was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains: *C. botulinum* Type C Bacterin-Toxoid, Mink Enteritis Virus Type 1, Mink Enteritis Virus Type 2, *P. aeruginosa* Serotype 5 Strain PA7G-485 and Strain PA7M-485-347, *P. aeruginosa* Serotype 7-8 Strain PA6M-485-JB and Strain PA6M-485-JA and Strain PA6G-485, *P. aeruginosa* Serotype 6 Strain PA5M-485-P and Strain PA5G-485. The adjuvant is Aluminum hydroxide hydrated for adsorption and the excipients are antifoam 1%, 1M citrate buffer, thimerosal (thiomersal) and water for injections.

The container/closure system consists of 625, 250 and 120 ml HDPE vials. The vials are composed of Olefin polymer as defined in 21 CFR 177.1520 and Ph.Eur. 3.1.5. Vials are closed with Ph.Eur. 3.2.9 type I bromobutyl rubber stoppers. Vials are sterilized by gamma irradiation, stoppers are sterilized with steam sterilization using validated equipment. The vials are sealed with an aluminum cap, which is sterilized by steam sterilization.
The choice of the pathogens, adjuvant and thiomersal as a preservative are justified. 
The inactivation process and the detection limit of the control of inactivation are correctly validated.

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
Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Ph. Eur. 2262 Guidelines; any deviation was adequately justified.
The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

D. Control tests during production
The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

E. Control Tests on the Finished Product
The tests performed on the final product conform to the relevant requirements; any deviation from these requirements is justified.
Batch to batch consistency is demonstrated. Other supportive data provided confirm the consistency of the production process.

F. Stability
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.
No in-use stability data are submitted, as the product is to be used immediately after broaching the container.

G. Other Information
None.
III. SAFETY ASSESSMENT

The application is made in accordance with Article 13.1 of the Directive 2001/82/EC, as amended. The generic product is identical to the reference product (auto-generic application). The raw materials used, the manufacturers and the manufacturing processes are the same.

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

Warning statements and precautions as listed in the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users, consumers and the environment.

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. The assessment concluded that the overall risk to the environment is estimated to be effectively zero, there is no necessity to conduct a phase II assessment. No warnings regarding risks to the environment are therefore required.

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.
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.

<table>
<thead>
<tr>
<th>Summary of change (Application number)</th>
<th>Section updated in Module 3</th>
<th>Approval date</th>
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<tbody>
<tr>
<td>Change in name of veterinary medicinal product in DK (NL/V/0227/001/IB/001)</td>
<td>N/A</td>
<td>1 March 2018</td>
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<tr>
<td>Addition of a manufacturing site for antigen production, formulation, primary packaging and secondary packaging (NL/V/0227/II/002/G)</td>
<td></td>
<td>14 November 2018</td>
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