MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE MEDICAMENTOS VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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

DECENTRALISED PROCEDURE

DRAFT PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

OPTOMEASE Vet 200 mg/ml concentrate for solution for fish treatment (UK, NO, DK, IE)

OPTOMEASE 200 mg/ml concentrate for solution for fish treatment (ES, EL)

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0370/001/DC
Name, strength and pharmaceutical form	Optomease Vet 200mg/ml concentrate for solution for fish treatment (UK, NO, DK, IE) Optomease 200mg/ml concentrate for solution for fish treatment (ES, EL)
Applicant	Virbac S.A. 1 Ère Avenue 2065M - LID 06511 Carros France
Active substance(s)	Benzocaine
ATC Vetcode	QN01A X92
Target species	Atlantic Salmon and Rainbow Trout
Indication for use	For the anaesthesia and sedation of salmon and trout. The product is not for use in open water and should always be used in an isolated treatment vessel.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	Day 210: 04/03/2020
Date product first authorised in the ReferenceMemberState (MRP only)	N/A
Concerned Member States for original procedure	DK, EL, IE, NO and UK

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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 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.

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II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 200 mg/ml of benzocaine as active substance, patent blue as colour, and the excipients dimethyl sulfoxide and propylene glycol as solvents

The container/closure system is a high-density polyethylene (HDPE) bottle with a HDPE outer and polypropylene (PP) inner child resistant cap. The bottle has included an integral doser.

The choice of the formulation and the presence of colour are 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 from 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 benzocaine, 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.

Scientific data and/or 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 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 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 product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13 (1) – Generic application of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, results of safety and residues tests are not required.

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

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

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of pharmacological studies are not required.

Toxicological Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of pharmacological studies are not required.

User Safety

A User Risk Assessment was provided and concluded that the exposure, hazards and risks from the use of the product are similar to those of the reference product and the same mitigation measures are included in the SPC and product literature. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. However, due to the presence of Benzocaine, a warning for pregnant women has been added.

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. The authorisation is granted conditioned to the environmental introduction concentration in water (EICaquatic expressed in µg/l) released from aquaculture facilities is always lower than 1 µg/l, according to the product literature.

This is achieved provided that the user strictly follows the recommendations of disposal of the product. The release should be controlled to achieve an appropriate dilution into the effluent that guarantees that the concentration of water released from aquaculture facilities is below 1 µg/l, thereby the risk in effluents is reduced to an acceptable level.

Adequate instructions are provided in the product literature.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because this application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended and both candidate and reference product are bioequivalent. It can be accepted that the withdrawal period as approved for the reference product, is also applicable to the generic product.

MRLs

Benzocaine is listed in table 1 of the Annex to Commission Regulation (EU) No 37/2010.

MRLs are listed below:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Benzocaine	Not applicable	All food producing species	No MRL required	For use as local anaesthetic only	No entry
		Salmonidae	No MRL required	Not applicable	

The excipients are included in table 1 of Commission Regulation (EU) 37/2010 (No MRL required).

Withdrawal Periods

Based on the data provided above, a withdrawal period of 7 degrees days for meat in Atlantic Salmon and Rainbow Trout and "Not for use in fish producing or intended to produce eggs for human consumption" are justified.

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

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 veterinary Heads of 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.

None