



FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

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“MUTUAL RECOGNITION” PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

12/01/16

French agency for food, environmental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1**PRODUCT SUMMARY**

EU Procedure number	FR/V/0296/001/MR
Name and pharmaceutical form	AVINEW NEO Effervescent tablet for suspension for oral and ocular administration and for spraying
Applicant	MERIAL
Active substance(s)	Live Newcastle Disease Virus, strain VG/GA-AVINEW
ATC Vetcode	QI01AD06
Target species	Chickens (broiler, future layer and future breeder pullets)
Indication for use	Active immunisation against Newcastle disease to reduce mortality and clinical signs associated with the disease

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website <http://www.ircp.anmv.anses.fr/>

MODULE 3**PUBLIC ASSESSMENT REPORT**

Legal basis of original application	New pharmaceutical form, application in accordance with §2d of Annex I of Commission Regulation 1234/2008
Date of completion of the original mutual recognition procedure	22 July 2015
Date product first authorised in the Reference Member State (MRP only)	17 September 2014
Concerned Member States for original procedure	AT, BE, DE, EL, ES, FI, IE, LU, NL, PT, UK

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.

Satisfactory evidence of the equivalence between the effervescent tablet and freeze-dried forms of this vaccine was provided. Hence, AVINEW NEO can be safely used in the target species; vaccination of chickens in lay is not recommended.

The product is safe for the user, the consumer and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

As equivalence between the effervescent tablet and freeze-dried forms of this vaccine was provided, there was no need to further demonstrate the efficacy of the product, when used as recommended.

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

II. QUALITY ASPECTS**A. Composition**

Each dose contains:

Active substance:

Live Newcastle disease virus, VG/GA-AVINEW strain $\geq 5.5 \log_{10}$ EID₅₀(*) (*)

EID₅₀: Egg Infective Dose 50 per cent.

Excipients:

Brilliant blue FCF (E 133), Casein hydrolysate, Mannitol, Polyvidone, Sucrose, Potassium dihydrogen phosphate, Dipotassium phosphate, Potassium glutamate, Bovine albumin fraction V, Purified water, Citric acid anhydrous, Sodium hydrogen

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carbonate, Magnesium stearate.

The vaccine is presented as effervescent tablets packed in an airtight aluminium blister, consisting of two aluminium foils heat-sealed tightly. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain and the formulation are justified.

The product is a novel 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 a live Newcastle disease virus, strain VG/GA-Avinew, an established active substance. 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.

Starting materials of non-biological origin used in production comply with the corresponding pharmacopoeia monographs or in-house specifications.

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

Certificates of suitability issued by the EDQM have been provided for the freeze-dried forms of this vaccine 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.

None of the new raw materials for the effervescent tablets are of biological origin from ruminants.

E. Control tests during production

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

F. 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. The tests include in particular appearance, disintegration time, pH, identification of the VG/GA-Avinew strain, determination of the infective titre, confirmation of the safety of the vaccine, sterility, purity, absence of extraneous agents and residual humidity.

The demonstration of the batch to batch consistency is based on the results of 3 batches produced according to the method described in the dossier. Other supportive data provided confirm the consistency of the production process.

G. 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.

The in-use shelf-life of the reconstituted vaccine is supported by the data provided.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

III. SAFETY ASSESSMENT

Satisfactory evidence of the equivalence between the effervescent tablet and freeze-dried forms of this vaccine was provided. Hence, the safety package of the freeze-dried forms, already assessed and approved, is applicable to AVINEW NEO.

The MAH made a classical sequential risk analysis approach to assess the risk of accidental ingestion of a tablet, with particular emphasis on the risk to children. The assessment concluded that any accidental ingestion is very unlikely.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

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IV. EFFICACY ASSESSMENT

Satisfactory evidence of the equivalence between the effervescent tablet and freeze-dried forms of this vaccine was provided. Hence, the efficacy package of the freeze-dried forms, already assessed and approved, is applicable to AVINEW NEO.

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.