United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Primun Salmonella E Lyophilisate for Use in Drinking Water for Chickens

Date Created: June 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Primun Salmonella E Lyophilisate for Use in Drinking Water for Chickens
Applicant	Laboratorios Calier, S.A., Barcelonès 26 (Pla del Ramassà), 08520 Les Franqueses del Vallès, Barcelona, Spain
Active substance(s)	*Salmonella enterica* subsp. *enterica* serovar Enteritidis-strain CAL 10 Sm+/Rif+/Ssq-
ATC Vetcode	QI01AE01
Target species	Chickens
Indication for use	Active immunisation to reduce colonisation of internal organs (spleen, liver, caeca and ovaries) and faecal excretion of Salmonella Enteritidis field strains. Onset of immunity: within 14 days after 1st vaccination and within 4 weeks after the 2ndand 3rd vaccination. Duration of immunity: until 80 weeks after the 3rd vaccination, when used according to the recommended vaccination schedule and until 40 weeks after the 4th vaccination, when used according to the recommended vaccination schedule.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 8 of VMRs 2013 (Schedule 1, Article 1) as amended.
Date of conclusion of the procedure	26/03/24

I. SCIENTIFIC OVERVIEW

This is a GB only full application for Primun Salmonella E Lyophilisate for Use in Drinking Water for Chickens.

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, any reactions observed are indicated in the SPC.[1] 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 [2] 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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains *Salmonella enterica* subsp. *enterica* serovar Enteritidis-strain CAL 10 Sm+/Rif+/Ssq- and the excipients skimmed milk, sucrose, gelatin, HEPES buffer and water for injections.

The container/closure system consists of Type I glass bottles closed with a bromobutyl rubber stopper and push tear-off aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain and the absence of preservative are justified.

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

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II.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.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is *Salmonella enterica* subsp. *enterica* serovar Enteritidis-strain CAL 10 Sm+/Rif+/Ssq-, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

Starting materials of non-biological origin used in production comply with Ph. Eur.

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.

Starting materials not listed in pharmacopoeias are in compliance with the Guidelines and specifications have been provided.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

The packaging materials comply with the relevant monographs.

II.C.4. Substances of Biological Origin

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.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

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

II.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. Other supportive data provided confirm the consistency of the production process.

II.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.

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

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 3 hours.
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

III. SAFETY ASSESSMENT

Laboratory trials

The safety of the administration of one dose, an overdose and the repeated administration of one dose in the target animal is demonstrated.

Effects on reproductive performance were examined. The data from the studies determine that the vaccine is not suitable for laying birds and within 3 weeks before the start of the laying period.

Specific studies were carried out to describe the spread, dissemination, reversion to virulence, biological properties, recombination or genetic reassortment of the vaccine strain.

The excipients used do not fall within the scope and no MRLs are required. Based on this information, a withdrawal period of 28 days for meat and offal has been proposed.

The interaction of the vaccine with simultaneous use of live vaccines against Gumboro disease, *Eimeria* and Marek disease was studied. An appropriate warning on the SPC is included.

Field studies

A field trial was carried out to demonstrate the safety and efficacy. The birds were administered three doses at one day old, 8 weeks and 19 weeks in drinking water. Primun was compared with a similar reference vaccine as a positive control group. Serological and environmental samples were negative for antibodies for *Salmonella*. Eggs were tested for transmission of *Salmonella* from week 26 until the end of the study. The vaccine can be considered safe when used in a standard dose in day old chickens under field conditions but only when used prior to lay as in the SPC.

Ecotoxicity

The applicant provided a Phase 1 environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

Clinical Studies

Laboratory Trials

The efficacy of the product has been demonstrated in laboratory studies in accordance with the relevant requirements.

Onset of Immunity

Four studies were provided to assess the onset of immunity of the vaccine. The data supports an onset of immunity of 14 days for excretion and colonisation after the first vaccination. The proposed onset of immunity claim of 14 days after the 3rd vaccination is supported by the data in one study.

Duration of Immunity

Two studies have been provided to assess the duration of immunity of the vaccine. The data supports an onset of immunity of 80 weeks for reduction in excretion and colonisation after the third vaccine.

Field Trials

A field trial was carried out to demonstrate the safety and efficacy. This trial is the same as described under Part III. In general, Primun SE may have a positive impact on birds in terms reduction of colonisation of the internal organs and excretion of *Salmonella* after challenge.

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 of the product is favourable.

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 Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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