



**Veterinary
Medicines
Directorate**

**United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

Lenzelta Suspension for Injection for Cattle

Date Created: February 2026

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Lenzelta Suspension for Injection for Cattle, Suspension for injection
Applicant	Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, 55216, Germany
Active substance(s)	<i>Escherichia coli</i> , serotype O111, strain J5, inactivated <i>Staphylococcus aureus</i> , strain DSM 4910, inactivated
ATC Vetcode	QI02AB17
Target species	Cattle
Indication for use	<p>For active immunisation of healthy cows and heifers, in herds of dairy cattle with repeated occurrence of mastitis, to reduce the incidence and severity of clinical mastitis caused by <i>Staphylococcus aureus</i> and <i>Escherichia coli</i>.</p> <ul style="list-style-type: none">• Onset of immunity: 4 weeks after completion of the primary vaccination course.• Duration of immunity: up to 6 months after completion of the primary vaccination course.

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 Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended.
Date of conclusion of the procedure	8/01/2026

I. SCIENTIFIC OVERVIEW

The product was submitted for a full application for authorisation in Great Britain (GB), in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended.

Lenzelta Suspension for Injection for Cattle contains inactivated *Escherichia coli*, serotype O111, strain J5 and inactivated *Staphylococcus aureus*, strain DSM 4910, both at a relative potency (RP) of ≥ 1 . RP is determined by comparing the antibody level with the antibody level in serum of mice prepared with a reference batch of vaccine compliant with the challenge test in target animals.

The product is indicated for the active immunisation of healthy cows and heifers, in herds of dairy cattle with repeated occurrence of mastitis, to reduce the incidence and severity of clinical mastitis caused by *Staphylococcus aureus* and *Escherichia coli*. The recommended administration protocol is to give one dose (2 ml) intramuscularly twice. The first dose should be given 45 days before the expected parturition date followed by the second dose 3 weeks after. This full vaccination schedule must be repeated with each pregnancy.

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 SPC¹. 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 efficacy² 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

¹ SPC – Summary of product Characteristics.

² Efficacy – The production of a desired or intended result.

The product contains inactivated *Escherichia coli* and inactivated *Staphylococcus aureus* and the excipients thiomersal, formaldehyde, sodium chloride and water for injections.

The container/closure system consists of either 10ml type I glass vials, 50ml & 100ml type II glass vials or 15ml, 60ml & 120ml high-density polyethylene (HDPE) vials with chlorobutyl rubber closures and aluminium or flip off caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the adjuvant, vaccine strain, inactivating agent and presence of preservative are justified.

The inactivation process and the detection limit of the control of inactivation are correctly validated.

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

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 substances are inactivated *Escherichia coli* and inactivated *Staphylococcus aureus*, novel active substances, supplied with specifications and certificates of analysis. The active substances are manufactured in accordance with the principles of good manufacturing practice.

Starting materials of non-biological origin used in production are provided with certificates of analysis or details of in-house testing, showing compliance with the monograph for each.

Biological starting materials used are supplied with certificates of analysis. They are appropriately screened for the absence of extraneous agents according to the guidelines.

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

Satisfactory certificate of analysis and drawings for the primary containers, rubber stoppers and aluminium caps were provided to show compliance with European Pharmacopoeia.

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. These include tests for appearance, sterility, air tightness, extractable volume, pH, potency, identity, content of aluminium, thiomersal and formaldehyde, and endotoxin assay.

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.

II.F. Stability

Stability data on the active substances have been provided in accordance with applicable regulatory 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 regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

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

G. Other Information

The shelf life of product as packaged for sale is 2 years. The shelf life after first opening the immediate packaging is 10 hours.

The product should be stored and transported refrigerated (2 °C – 8 °C). It should be protected from frost and light.

III. SAFETY ASSESSMENT

Laboratory trials

One laboratory safety study was performed to evaluate the safety of a single dose, repeated dose and safety of reproductive performance in accordance with the relevant guideline. This was carried out to GLP in the target species, using the recommended route of administration.

The batch of vaccine used in the safety study contained the maximum antigen content and was prepared according to the manufacturing process.

In the study, 16 pregnant heifers were divided into 2 groups, with group 1 being vaccinated with three individual doses (2 ml) of the vaccine and group 2 receiving injections with sterile saline. The data presented showed that no animal died or showed notable signs of disease from causes attributed to the vaccine.

Results indicated that the rectal temperature of vaccinated animals had a maximum average increase of 0.2°C. In the vaccinated animals, no local reactions were observed after the administration of the first dose. After the administration of the second dose, swelling at the injection site of 0 - 2 cm was observed in one animal two days after the vaccination. This swelling increased to average 2 - 5 cm² and decreased gradually, with no swelling noted on day 15. No swelling was observed after administration of the third dose. No systemic adverse reactions were observed after administration of vaccine. Elevation of rectal temperature and injection site reactions are reflected in the SPC.

Safety of the vaccine on reproductive performance was with length of gestation period in pregnant cows, number of live and dead calves, and the health condition of calves born from these cows assessed. All animals from the vaccinated group had a live calf and no adverse effect on the gestation, during calving and on the health of the newborn calves was observed. The study indicates no negative effects of vaccination on the outcome of pregnancy. The information provided supports the use of the vaccine in pregnant animals and appropriate wording is included in the SPC. Safety of vaccine in lactating animals was not evaluated, and this is reflected in the SPC.

There are no data suggesting that this product might adversely affect the immune system of the vaccinated animal or its progeny therefore a specific study was not carried out.

The vaccine is inactivated and thus the specific tests to be performed for live vaccines are not applicable.

The adjuvant and excipients used are either allowed substances for which no Maximum Residue Limits (MRLs) are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used. Based on this information, there is no withdrawal period for the product.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

Field studies

One study was conducted to demonstrate safety and efficacy of vaccination against mastitis caused by *E. coli* and *S. aureus* under field conditions. The study was carried out according to the requirements of the Ph. Eur. using a batch prepared according to the manufacturing process containing a standard antigen content of both the antigens.

The study was conducted in the Czech Republic in accordance with GCP. The vaccine was administered to pregnant heifers when the vaccine was administered as per the recommended vaccination schedule.

In the study 32 pregnant heifers were either vaccinated or used as a control, not administered a placebo. Safety was assessed by observing clinical signs, local reactions and parturition, and the viability of the newborn calves.

The results indicated that the maximum average increase in rectal temperature was 0.5°C and the maximum individual increase in rectal temperature was 1.5°C in one animal which return to normal within 24 hours. The description and frequency of the adverse events is present in section 3.6 of the SPC based on the data from the laboratory and field safety studies. The local reaction at the injection site was assessed in the vaccinated group. No local reactions were recorded at the injection sites after administration of the first and second dose. No systemic adverse reactions were observed after administration of the vaccine doses for the duration of the study.

No adverse effects on the gestation, parturition and health of the newborn calves were reported. In conclusion, the safety field trial supports the results of the laboratory safety study.

Ecotoxicity

The applicant provided a Phase 1 environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

The assessment concluded that the product is not expected to pose a risk for the environment when used according to the SPC. No warnings regarding are therefore required.

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. Three studies were conducted to investigate efficacy which included two laboratory studies and one field trial.

Laboratory studies to determine onset of immunity (OOI) and duration of immunity (DOI) were well documented and carried out in pregnant heifers using batches of vaccine containing the minimum titre for both the antigens.

Onset of Immunity

One study investigated OOI with *E. coli* and *S. aureus* on the 6th day post-parturition. The study was conducted in accordance with necessary guidelines followed the recommended vaccination schedule. The vaccine batch used was prepared according to the manufacturing process and contained minimum titre for both the antigens.

Two groups of 16 pregnant heifers were divided into vaccinated or control groups. The control used was sterile PBS solution injection. On day 6 after parturition, one group was challenged with *Escherichia coli* and the other with

Staphylococcus aureus, via the intramammary route. Blood samples were collected on the day of vaccination, on the day of challenge and 10 days before the expected parturition date to detect antibodies. All animals were observed daily for 7 days for clinical signs of mastitis, general health status, rectal temperature and milk samples were collected for somatic cell count.

The results indicated that both vaccinated groups, challenged with either *E. coli* or *S. aureus*, showed a statistically significant reduction in rectal temperatures and indicators of mastitis compared to the control groups. There was a decrease in somatic cell count in milk samples in the vaccinated animals compared to the non-vaccinated animals.

This study supports the onset of immunity of 4 weeks after the second injection to reduce the incidence and severity of the clinical signs of mastitis.

Duration of Immunity

One GLP study investigated DOI, with *E. coli* and *S. aureus* challenge performed in separate groups, 150 days (5 months) post-parturition. The vaccine batch used was prepared according to the manufacturing process and contained minimum titre for both the antigens.

Two groups of 16 pregnant heifers were divided into vaccinated or control groups. 5 months post-parturition the cows one group was challenged with *E. coli* and the other with *S. aureus*, via the intramammary route. All animals were observed daily for 7 days for symptoms of the onset of acute mastitis, rectal temperature and milk samples were collected for somatic cell count. Blood samples were collected on the day of vaccination, on study day 51 (6 days post parturition) and on study day 195 (before the challenge) from both the vaccinated and control groups to detect antibodies. The DOI study ended on study day 203.

The results showed that for both vaccinated groups, challenged with either *E. coli* or *S. aureus*, there was a statistically significant reduction in rectal temperature and indicators of mastitis and a reduction in somatic cell counts.

Therefore, this study supports the duration of immunity of up to 6 months after the second injection to reduce the incidence and severity of the clinical signs of mastitis.

Field Trials

To evaluate efficacy of the product in pregnant heifers, under field conditions, a combined safety and efficacy field trial was conducted. The vaccine batch used was prepared according to the manufacturing process and contained standard antigen content for both antigens.

The study was conducted in two regions of the Czech Republic. The efficacy of the vaccine was evaluated by observing the clinical signs of acute mastitis, somatic cell counts and myeloperoxidase enzyme activity in milk samples and serology to detect antibody levels. The field trial ended on 150 days post parturition.

The results indicated that the occurrence of mastitis was less frequent in the vaccinated animals when compared to the control group. Somatic cell counts were significantly lower in the vaccinated animals than in the control animals. The results of the field trial support the results of the laboratory efficacy studies.

In conclusion, the efficacy studies support an OOI of 4 weeks after the second injection and DOI of 6 months after the second injection in the target animals, following the recommended vaccination schedule.

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.

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

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.

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