1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lenzelta suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:
Escherichia coli, serotype O111, strain J5, inactivated: RP ≥ 1*
Staphylococcus aureus, strain DSM 4910, inactivated: RP ≥ 1*

* Relative potency (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.

Adjuvant:
Aluminum hydroxide gel 2 %: 0.4 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
Formaldehyde	≤ 1 mg
Sodium chloride	-
Water for injections	-

A light liquid with greyish sediment. Grey turbid liquid after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows and heifers).

3.2 Indications for use for each target species

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 *Staphylococcus aureus* and *Escherichia. coli*.

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.

3.3 Contraindications

None.

3.4 Special warnings

The whole herd should be immunised.
Vaccination must be considered as one part of a comprehensive preventive mastitis control programme, which should address all factors important for mammary gland health (e.g. milking technique, drying off and breeding management, hygiene, nutrition, housing, bedding, cow comfort, air and water quality, health monitoring) and other relevant management practices.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Seek medical advice if a local reaction occurs following accidental self-injection and show the package leaflet to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle (cows and heifers):

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1] Elevated temperature[2]

[1] swelling (up to 5 cm^2) for up to 2 weeks.
[2] a slight and transient increase in body temperature up to 1.5 °C may occur and disappear spontaneously within in the first 24 hours after the injection.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during the last trimester of pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

Intramuscular use.

Allow the vaccine to reach a temperature of 15 – 25 °C and shake the vial slightly before administration.

Administer one dose (2 ml) intramuscularly according to the following schedule:
- First dose: 45 days before expected parturition date.
- Second dose: 3 weeks after the first administration.

It is recommended to administer each dose on alternate sides.
This full vaccination schedule must be repeated with each pregnancy.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AB17

To stimulate active immunity against strains of *Staphylococcus aureus* and *E. coli* that cause bovine mastitis.
Under field conditions, a reduction of the Somatic Cell Count (SCC) in vaccinated cows was observed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 10 hours

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from frost.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vials of 3 ml or 10 ml with chlorobutyl rubber closure and aluminium or flip off caps.
Type II glass vials of 50 or 100 ml with chlorobutyl rubber closure and aluminium or flip off caps.
Translucent plastic (HDPE) vials of 15, 60 or 120 ml with chlorobutyl rubber closure and aluminium or flip off caps.

Plastic box of 10 glass vials of 1 dose (2 ml), 5 doses (10 ml) or 10 plastic vials of 5 doses (10 ml).
Cardboard box of 1 glass or plastic vial of 5 doses (10 ml), 25 doses (50 ml), 50 doses (100 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/082/001

8. DATE OF FIRST AUTHORISATION

05/12/2025

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).