B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Lenzelta suspension for injection for cattle

2. 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:
Aluminium hydroxide gel 2%: 0.4 ml

Excipients:
Thiomersal: 0.2 mg
Formaldehyde: ≤ 1 mg

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

3. Target species

Cattle (cows and heifers).

4. Indications for use

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.

5. Contraindications

None.

6. 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.

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

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

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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 the first 24 hours after the injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intramuscular (i.m.) use.

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.

9. Advice on correct administration

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

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Protect from frost.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging:10 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Bioveta, a,.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

Local representative and contact details to report suspected adverse events:

17. Other information

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.