

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Plastic box of 10 glass or 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)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Lenzelta suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose (2 ml) contains:

*Escherichia coli*, serotype O111, strain J5, inactivated: RP  $\geq$  1

*Staphylococcus aureus*, strain DSM 4910, inactivated: RP  $\geq$  1

**3. PACKAGE SIZE**

10 x 5 doses (10 x 10 ml)

1 x 5 doses (10 ml)

1 x 25 doses (50 ml)

1 x 50 doses (100 ml)

**4. TARGET SPECIES**

Cattle (cows and heifers).

**5. INDICATIONS**

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**6. ROUTES OF ADMINISTRATION**

Intramuscular use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: Zero days

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 10 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Protect from frost.  
Protect from light.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Vetmedica GmbH

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**100 ml vial (50 doses)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Lenzelta suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose (2 ml) contains:

*Escherichia coli*, serotype O111, strain J5, inactivated: RP  $\geq$  1

*Staphylococcus aureus*, strain DSM 4910, inactivated: RP  $\geq$  1

50 doses (100 ml)

**3. TARGET SPECIES**

Cattle (cows and heifers).

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**i.m. use.**

**5. WITHDRAWAL PERIODS**

Withdrawal period: Zero days.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 10 hours.

**7. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Protect from frost.

Protect from light.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**



**9. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vial of 5 doses (10 ml) and 25 doses (50 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Lenzelta

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

*E. coli, S. aureus*

5 doses

25 doses

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 10 hours.