

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard with wipes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INTRAMAR Lacto 200 mg + 50 mg + 10 mg intramammary suspension (AT, BE, CY, CZ, DE, GR, ES, FR, HR, HU, IT, LT, LU, LV, PL, PT, RO, SI, SK)

MASTIC Lacto 200 mg + 50 mg + 10 mg intramammary suspension for cattle (IE, UK (NI))

2. STATEMENT OF ACTIVE SUBSTANCES

Each intramammary syringe (3 g) contains:

Amoxicillin (as amoxicillin trihydrate)	200.0 mg
Clavulanic acid (as potassium clavulanate)	50.0 mg
Prednisolone	10.0 mg

3. PACKAGE SIZE

24 intramammary syringes

Each package includes 24 disinfectant wipes moistened with 65% v/v isopropyl alcohol solution to clean teats.

4. TARGET SPECIES

Cattle (lactating cows).



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 7 days.

Milk: 84 hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store in a dry place.

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

Bioveta, a.s.

Logo



14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard without wipes}

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Logo



14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label - syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INTRAMAR Lacto (AT, BE, CY, CZ, DE, GR, ES, FR, HR, HU, IT, LT, LU, LV, PL, PT, RO, SI, SK)

MASTIC Lacto (IE, UK (NI))

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin 200.0 mg/syringe

Clavulanic acid 50.0 mg/syringe

Prednisolone 10.0 mg/syringe

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

Logo

