B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

INTRAMAR Lacto 200 mg + 50 mg + 10 mg intramammary suspension for cattle (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. Composition

Each intramammary syringe (3 g) contains:

Active substances:

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

Cream to yellow-brown oily intramammary suspension.

3. Target species

Cattle (lactating cows).

4. Indications for use

For the treatment of clinical mastitis including cases associated with infections with the following pathogens:
Staphylococci (including β-lactamase producing strains)
Streptococci (including *S. agalactiae, S. dysgalactiae* and *S. uberis*)
Escherichia coli (including β-lactamase producing strains)

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals which are known to be hypersensitive to β-lactam antibiotics.

6. Special warnings

Special warnings:
Do not use in cases associated with *Pseudomonas*.
The veterinary medicinal product should be used for treatment of clinical mastitis only.
Avoid use of the veterinary medicinal product in herds where no β-lactamase producing *Staphylococci* strains have been isolated.
Cross-resistance has been shown between amoxicillin/clavulanic acid and β-lactam antibiotics. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to β-lactam antibiotics because its effectiveness may be reduced.
Most ESBL and AmpC ß-lactamase-producing *E. coli* strains may not be inhibited by the combination of amoxicillin/clavulanic acid. The combination of amoxicillin and clavulanic acid is not effective against methicillin-resistant strains of *S. aureus* (MRSA).

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
The feeding of waste milk containing residues of amoxicillin and clavulanic acid to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity to penicillins and/or cephalosporins should avoid contact with the veterinary medicinal product.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty breathing are serious symptoms and require urgent medical attention.
This veterinary medicinal product may cause irritation of skin and eyes. Avoid contact with skin and eyes. In case of contact with skin or eyes, flush the affected area with plenty of clean water.
The cleaning wipes supplied with the veterinary medicinal product contain isopropyl alcohol, which may cause skin or eye irritation in some people.
Personal protective equipment consisting of gloves should be used when handling the veterinary medicinal product and cleaning wipes.
Wash hands after use.

Special precautions for the protection of the environment:
Due to the endocrine-disrupting potential of prednisolone, the veterinary medicinal product may be dangerous to fish and other aquatic organisms. Consequently, treated animals should not have access to watercourses during the first 12 hours after treatment.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
No adverse reactions are to be expected from an accidental overdose.

Major incompatibilities:
Not applicable.

7. Adverse events

Cattle (lactating cows):
None known.

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 the local representative of the marketing authorisation holder 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

Intramammary use.
The content of one syringe should be infused into each affected quarter via the teat canal, immediately after milking, at 12 hour intervals for three consecutive milkings.

9. Advice on correct administration

Milk out the infected quarters. Before infusion, the teat end should be cleaned and disinfected with the enclosed disinfectant wipe or a cleaning towel and an appropriate disinfectant. The content of one syringe should be infused into each affected quarter via the teat canal, immediately after milking, at 12 hour intervals for three consecutive milkings.
In cases of infections caused by *Staphylococcus aureus*, a longer course of antibacterial therapy may be required. Therefore, overall treatment length must be at the veterinarian's discretion but should be long enough to ensure complete resolution of intramammary infection.

10. Withdrawal periods

Meat and offal: 7 days.
Milk: 84 hours.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as prednisolone may be dangerous for fish and other aquatic organisms.

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 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

Package size:
Carton box of 24 syringes.
Carton box of 24 syringes and 24 disinfectant wipes moistened with 65% v/v isopropyl alcohol solution (2.4 ml/wipe) to clean teats.
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 and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic
Tel: + 420 517 318 911
E-mail: reklamace@bioveta.cz

<Local representatives< and contact details to report suspected adverse reactions>:>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Environmental properties
Prednisolone has endocrine-disrupting potential and therefore may be dangerous to fish and other aquatic organisms.