1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTIC DRY COW 600 g intramammary suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intramammary syringe (3.6 g) contains:
Active substance:
Cloxacillin 600 mg
(equivalent to cloxacillin benzathine 765.42 mg)

Excipients:

Qualitative composition of excipients and other constituents
Stearic acid
Aluminium stearate
Paraffin, liquid

White to yellowish oily suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dry cow)

3.2 Indications for use for each target species

Treatment of existing intramammary infections in cows at drying off and protection against new infections that may occur during the dry period.

3.3 Contraindications

Do not use in lactating cows.
Do not use in cases of hypersensitivity to penicillins, other beta-lactams or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on recent susceptibility profile of the target pathogens at farm level. If this is not possible, therapy should be based on epidemiological information and on knowledge of the susceptibility of the target pathogens at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
An increasing trend in the prevalence of resistance of *Streptococcus uberis* isolated from bovine mastitis has been identified in some EU countries. The use of cloxacillin is not recommended on dairy farms with presence of methicillin-resistant staphylococci (MRSA or MR-NAS).
Use of the veterinary medicinal product deviating from the instructions given in this Summary of Product Characteristics (SPC) may increase the prevalence of bacteria resistant to cloxacillin and may

decrease the effectiveness of treatment with other beta-lactams and cephalosporins due to the potential for cross-resistance.
The feeding of waste milk containing residues of cloxacillin 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 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, rinse 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 worn when handling the veterinary medicinal product and cleaning wipes.
Wash hands after use.

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

3.6 Adverse events

Cattle (dry cow)
None known.

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 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

Lactation:
Do not use in lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramammary use.

Administer the contents of one intramammary syringe into each quarter immediately after the last milking before drying-off. Thoroughly clean and disinfect each teat and teat end with the provided disinfectant wipe before administering the veterinary medicinal product. Use a new disinfectant wipe for each teat. Do not use disinfectant wipes on teats with visible lesions.
After administration, it is advisable to dip the teats in an antiseptic.

Preparation and use of a short tip: Grasp the cover cap between the thumb and forefinger, bend it over and remove it. Gently insert only the white part of the tip into the teat canal. Gently depress the plunger with slight, continuous pressure until the teat canal is filled evenly. Following administration, a gentle massage from the teat end upwards is recommended to distribute the product into the milk cistern of the treated udder quarter.

Preparation and use of a conventional tip: Grasp the cover cap bottom between the thumb and forefinger, bend it over, press down and remove it. Gently depress the plunger with slight, continuous pressure until the teat canal is filled evenly.

Never touch the exposed tip with your fingers!
The syringe must only be used once.

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

Overdose is very unlikely, as the entire contents of the intramammary syringe are intended for single administration. No adverse reactions were observed after accidental overdose.

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

Meat and offal: 28 days
Milk: 96 hours after calving if the dry period is 42 days or longer.
42 days plus 96 hours after treatment in cows with a dry period shorter than 42 days.
The product must not be used during lactation, but only during dry period.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ51CF02

4.2 Pharmacodynamics

Cloxacillin is a semisynthetic bactericidal antibiotic from the group of isoxazolyl penicillins. It is effective against Gram-positive microorganisms causing mastitis, including penicillinase-producing strains. The spectrum of action includes streptococci, including *Streptococcus agalactiae*, staphylococci (including penicillinase-producing strains) and *Trueperella pyogenes (*formerly *Corynebacterium pyogenes).* It has no effect on the genus *Staphylococcus* spp. with methicillin resistance (MRSA, MR-NAS).

There are three main mechanisms of resistance to beta-lactam antibiotics: production of beta-lactamases, reduced cell wall permeability and efflux and modification of target penicillin-binding proteins (PBPs) of the cell wall. Resistance can be encoded chromosomally, but can also be transmitted by mobile genetic elements. Other factors that increase the risk of resistance include the ability to form a biofilm. Cloxacillin shows partial cross-resistance with other penicillin antibiotics and cephalosporins.

4.3 Pharmacokinetics

The product maintains an effective concentration of the active substance in the mammary gland for 6 to 7 weeks.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: use immediately.

5.3 Special precautions for storage

Store below 25 °C.
Protect from frost.

5.4 Nature and composition of immediate packaging

White 4.5 ml LDPE intramammary syringe containing 3.6 g of the suspension, fitted with a white LDPE cap, LDPE cuff and a LDPE plunger. Packed in a carton box containing 24 intramammary syringes. Each package includes 24 disinfectant wipes moistened with 65% v/v isopropyl alcohol solution (2.4 ml/wipe) to clean teats.

Package size:
Carton box with 24 intramammary syringes and 24 disinfectant wipes moistened with 65% v/v isopropyl alcohol solution (2.4 ml/wipe).

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

Bioveta, a. s.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22028/012/001

8. DATE OF FIRST AUTHORISATION

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

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*).