

PACKAGE LEAFLET FOR:

INTRAMAR DRY COW 600 mg Intramammary Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

INTRAMAR DRY COW 600 mg Intramammary Suspension for Cattle
Cloxacillin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each applicator (3.6 g) contains:

Active substance:

Cloxacillin 600 mg
(equivalent to cloxacillin benzathine 765.42 mg)

A white to yellow oily suspension.

4. INDICATION(S)

For treatment of existing intramammary infections of cows in the dry period and to provide protection against new infections that may occur during the dry period.

5. CONTRAINDICATIONS

Do not use in lactating cows.

6. ADVERSE REACTIONS

None known.

If you notice any side effects in your animal or you think that the medicine has not worked, please inform your veterinary surgeon. You can report adverse reactions electronically via the form on the ÚSKVBL's website or directly to:

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
(*Institute for State Control of Biologicals and Medicines*)

Hudcova 56a

621 00 Brno

Mail: adr@uskvbl.cz

Website: <http://www.uskvbl.cz/cs/farmakovigilance>

7. TARGET SPECIES

Cattle (dairy cows during the dry period)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Apply the contents of one applicator to each quarter immediately after the last milking before drying-off.

9. ADVICE ON CORRECT ADMINISTRATION

Intramammary administration.

Thoroughly clean and disinfect the teat end with the included disinfectant wipe before administering the product. Do not use disinfectant wipes on teats with visible lesions. Use a new disinfectant wipe for each teat.

After administration, it is advisable to soak the teats in an antiseptic.

Preparation and use of a short tip: Grasp the cover cap between the thumb and forefinger, bend over and remove. Introduce only the white part of the tip into the teat canal. Apply the product carefully under slight pressure, until the teat canal is filled evenly. After application it is recommended to do a short massage from the tip of the teat to 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 over, press down and remove. Apply the product carefully under slight pressure, until the teat canal is filled evenly.

Never touch the exposed tip with your fingers!

The applicator may only be used once.

10. WITHDRAWAL PERIOD(S)

Meat: 28 days

Milk: 96 hours after delivery, 42 days or more in the case of a dry period.

42 days plus 96 hours after treatment in cows with a dry period of less than 42 days.

The product must not be used in lactation, but only during the dry period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C.

Protect from frost.

Shelf life after first opening the immediate packaging: Use immediately.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

Official and local antimicrobial policies should be taken into account when the product is used.

Use of the product should be based on cultivation and susceptibility testing of the microorganisms coming from diseases on the farm. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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 methicillin-resistant strains of *Staphylococcus aureus* (MRSA). Use of the product deviating from the instructions given in this Package Leaflet 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.

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 cephalosporins should avoid contact with the veterinary medicinal product. If you experience post-exposure symptoms such as skin rash, seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips, eyes or difficulty breathing are serious symptoms and require immediate medical attention.

Avoid contact with skin and eyes. When handling the veterinary medicinal product, personal protective equipment consisting of rubber gloves should be used. In case of accidental contact with skin or eyes rinse with plenty of water.

The cleaning wipes supplied with this product contain isopropyl alcohol. In case of known hypersensitivity to isopropyl alcohol, use protective gloves. Avoid contact with eyes as isopropyl alcohol may cause eye irritation.

Wash hands after use.

Pregnancy and lactation:

Do not use in lactating animals.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Overdose is very unlikely because the entire content of the applicator is always applied.

No adverse reactions were observed after accidental overdose.

Incompatibilities:

None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only.

Veterinary medicinal product subject to prescription.

Pack size: 24 pieces of applicators The package includes 24 pcs of disinfectant wipes to clean teats. The enclosed wipes are moistened with a 65% v/v isopropyl alcohol solution (2.4 ml/wipe).