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Moraxella bovoculi SOLUTION!

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MAXI/GUARD® Pinkeye Bacterin has earned the trust of bovine practitioners as the preferred pinkeye preventative when the disease is caused solely by M. bovis. However, the problem can be caused by the combination of M. bovis and M. bovoculi bacteria. Unfortunately, no commercial vaccines provide that coverage. When M. bovoculi is present, your best option is utilizing MAXI/GUARD® along with the Addison Autogenous Program. We can assist you from diagnosing the problem to creating the solution!

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Introducing lmrestor™ (pegbovigrastim injection)—the first-of-its-kind immune restorative for periparturient dairy cows and heifers, available only by veterinary prescription.

Before using this product, please consult the product insert, a summary of which follows:

DESCRIPTION: lmrestor is a sterile injectable formulation of pegbovigrastim (an immunomodulator, bovine granulocyte stimulating factor) in single-dose syringes. Each syringe of lmrestor contains pegbovigrastim (15 mg), L-arginine (40 mg), and citric acid monohydrate (7.5 mg).

INDICATIONS FOR USE: For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

DOSE AND ADMINISTRATION: This is a two-dose regimen. The same dose is used regardless of cow/heifer body weight. Remove surface dirt from the injection site area before injecting. Inject the entire contents of the syringe subcutaneously. Do not reuse the syringe.

Administer the first dose (syringe) 7 days prior to the cow’s or heifer’s anticipated calving date. If necessary, the first dose may be administered within a range of 4 to 10 days prior to the anticipated calving date to accommodate management protocols. Administer the second dose (syringe) within 24 hours after calving.

Animals that calve either less than or more than 7 days after the first dose should receive the second dose within 24 hours after calving. Prior to administration, lmrestor should be visually inspected for particulate matter and discoloration. lmrestor is a clear, colorless solution and may contain a few small, translucent or white particles. lmrestor should not be used if it is discolored or cloudy, or if other particulate matter is present. Do not shake or tap the syringe prior to use.

WARNINGS:

> RESIDUE WARNING: No withdrawal period or milk discard time is required when used according to the labeling.


USER SAFETY WARNINGS: In case of accidental self-injection, wash the site of injection thoroughly with clean running water. Foreign proteins such as pegbovigrastim have the potential to cause anaphylactic-type reactions. If you experience swelling or redness of the site of exposure, or more severe reactions such as shortness of breath, seek medical attention immediately and take the package insert with you. Report the event to Elanco Animal Health at 1-800-438-4441. To obtain a Safety Data Sheet, contact Elanco Animal Health at 1-800-438-4441.

PRECAUTIONS: Do not use lmrestor to treat cows with clinical mastitis because effectiveness has not been demonstrated for this use.

ADVERSE REACTIONS: Some cases of hypersensitivity-type reactions have been observed in studies outside the United States within five minutes to two hours, occurring most often after the first administration of lmrestor. Clinical signs may include elevated respiratory rate, dyspnea, urticae, swelling, dependent edema, swollen mucous membranes, and/or hypereosinophilia, and, rarely death. These reactions resolve within hours of onset with or without therapeutic intervention and have not been shown to recur with subsequent injections of lmrestor.

Adverse ulcerations/erosions were observed in the Margin of Safety studies. (See Target Animal Safety section.)

To report a suspected adverse drug event, contact Elanco Animal Health at 1-800-438-4441. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-1075 or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

EFFECTIVENESS: The effectiveness of lmrestor for the reduction in the incidence of clinical mastitis was demonstrated in a multi-site natural infection field study conducted at four sites in the U.S. and one site in France. A total of 801 healthy periparturient commercial dairy heifers and cows were enrolled and treated with lmrestor or saline by subcutaneous injection in the neck when they were identified as being approximately 7 days before their anticipated calving date (Day -7), and again within 24 hours after calving (Day 0). Each quarter of each enrolled animal was evaluated at each milking from Days 3 to 30 to monitor the development of clinical mastitis. Animals developing clinical mastitis (using quarter health, milk quality, and California Mastitis Test (CMT) evaluation) through Day 30 were classified as treatment failures. Administration of lmrestor resulted in a statistically significant difference (p < 0.05) in the incidence of clinical mastitis (treatment failure rates across all five sites) with a difference in favor of the lmrestor-treated group (failure rate: 60/331 = 18.13%) compared to the saline-treated group (failure rate: 85/338 = 25.19%).

STORAGE INFORMATION: Store under refrigeration (2° to 8°C, 36° to 46°F). DO NOT FREEZE. Avoid prolonged exposure to sunlight. Excursions of up to 24 hours at room temperature (15° to 30°C, 59° to 86°F) are allowed after receipt.

DISPOSAL: Disposal of used syringes is a leach-resistant, puncture-resistant container in accordance with applicable Federal, state and local regulations.

HOW SUPPLIED: 10, 50 or 100 single-dose syringe packages with each syringe containing 15 mg of pegbovigrastim.

NADA 141-392. Approved by FDA.

Manufactured for Elanco Animal Health, a division of Elanco Lilly and Company, Indianapolis, IN 46258.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-800-438-4441.

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Even the best producers need a little help protecting their dairy herds.