pathogens are shown in Table 1.

**DESCRIPTION**

Pirlimycin hydrochloride is a lincosaminide antibiotic.

**Chemical Structure of Pirlimycin Hydrochloride**

![Chemical Structure of Pirlimycin Hydrochloride](https://example.com/chemicalstructure.png)

**Chemical Name of Pirlimycin Hydrochloride**

Methyl(2S)-7-chloro-6,7,8-tridecynyl-ethyl-2-piperidinyllcarbonate(aminoglycone)-1-thio-l-threo-±-D-galacto-octopyranoside monohydrate.

**ADVERSE REACTIONS**

Technique can result in the infusion of environmental mastitis pathogens not sensitive to pirlimycin. When using extended duration therapy with PIRSUE Sterile Solution, failure to thoroughly clean quarters and to use aseptic infusion technique can result in the infusion of environmental mastitis pathogens not sensitive to pirlimycin.

**INDICATIONS FOR USE**

**FOR USE IN ANIMALS ONLY - NOT FOR HUMAN USE**

**WARNING**

Choose the desired insertion length (full or partial) and gently insert the tip into the teat canal. Carefully push the plunger to infuse the solution into the milk canal. Following infusion, dip all quarters with an antiseptic teat dip. Cows with systemic clinical signs caused by mastitis should receive other appropriate therapy under the direction of a licensed veterinarian.

**Administration**

**Teat End Preparation:** Wash thoroughly with water containing a suitable disinfectant. Dry the teats thoroughly. Milk out the udder completely. Using the alcohol pad provided, wipe the teat end of the affected quarters, using a separate pad for each teat. Allow sufficient time (at least 5 to 10 seconds) for the alcohol to dry. Use of protective gloves by persons applying treatment is recommended as an aseptic infusion technique.

**Important Considerations for Extended Therapy:** For extended duration of therapy, infuse only quarters known to be infected with label pathogens. Do not concurrently infuse unlabeled low SCC quarters of the same cow. Prepare the teats using the above instructions, and ensure that the PIRSUE Sterile Solution using aseptic infusion technique and partial insertion (see diagram below).

**Infusion:** The Plastet disposable syringe is designed to provide the choice of either insertion of the full cannula as has traditionally been practiced, or insertion of no more than 1/8 inch of the cannula, as reported by Gertler, R.J., et al., 1987. Current Concepts of Bovine Mastitis, 3rd Edition, National Mastitis Council, Arlington, VA.

- **Full insertion:** Remove the white end cap by pulling straight up as shown. Gently insert the full cannula into the teat canal.
- **Partial insertion:** Remove the white end cap by pulling straight up as shown. Gently insert the exposed white tip into the teat canal.

**DISCARD EMPTY CONTAINER; DO NOT REUSE**

**KEEP OUT OF REACH OF CHILDREN**

**RESIDUE WARNINGS**

- **Milk taken from animals during treatment and for 36 hours after the last treatment must not be used for food regardless of treatment duration.**
- **Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days.**
- **Following any extended duration of therapy (infusion longer than twice at a 24-hour interval), treated animals must not be slaughtered for 21 days.**
- **Use of this product in a manner other than that indicated under DOSAGE might result in violative residues.**

**PRECAUTION**

When using extended duration therapy with PIRSUE Sterile Solution, failure to thoroughly clean quarters and to use aseptic infusion technique can result in the infusion of environmental mastitis pathogens not sensitive to pirlimycin.

**RECOMMENDATIONS FOR PREVENTION OF AMENORRHEA**

- **Milk from cows treated during the 24-hour period following treatment must not be used for food.**
- **Milk from cows treated for 24 hours or more following treatment must not be used for food.**
- **Milk from cows treated for 48 hours or more following treatment must not be used for food.**

**EFFECTIVENESS**

The effectiveness of pirlimycin was demonstrated in a field dose response study in lactating dairy cattle with clinical mastitis. Three investigators enrolled 486 cows from 39 herds. Cows with abnormal milk (clots, flakes) and with or without udder clinical signs (swelling, redness, or soreness) were enrolled and treated, regardless of the mastitis pathogens isolated or the pre-treatment somatic cell count. Cows were treated (in the affected quarter(s)) at 50, 100, or 200 mg of pirlimycin twice at a 24-hour interval. A non-treated control group was included. In this study, an individual quarter was cured if it had normal milk, no udder clinical signs, and if the milk was negative for any mastitis pathogens at 10 days post-treatment. If no bacteria were isolated pre-treatment, a decrease in somatic cell count was required. A cow was cured if all enroled quarters in that cow were cured. Three treatment levels had significantly greater cow cure rates than the non-treated control group. Based on this study, the dose of 50 mg of pirlimycin per quarter administered twice at a 24-hour interval was determined to be the effective dose for the treatment of clinical mastitis.

**Animal Safety**

Two parallel studies addressing the safety of pirlimycin administered at dosages of 50 mg or 200 mg (4x) into all four quarters twice at a 24-hour interval indicate that the formulation is safe and non-irritating to the bovine udder. Safety observations were also made during the clinical effectiveness study. No udder irritation was noted due to intramammary infusion with pirlimycin during these studies. An additional study was conducted to determine the safety of extended duration therapy. Twenty lactating Holstein cows, first lactation or greater, at various milk production levels, and with no evidence of clinical mastitis were enrolled and treated with pirlimycin administered at a dosage of 50 mg/quarter in all four quarters daily for eight consecutive days. Cows were monitored for general health, changes in milk production and quality, and signs of udder irritation for a total of 14 days, beginning three days prior to the first treatment. Milk production was not affected by treatment. SCCs of treated cows were statistically significantly increased post-treatment relative to the pre-treatment level. A total of 24 pirlimycin-treated cows (32% in 15 cows had increased SCIs (>200,000 cells/mL), for at least two consecutive milkings. Of these, six treated cows (8 quarters) had a concurrent bacterial infection attributable to a mastitis pathogen. Under irritation occurred in seven pirlimycin-treated cows (10 quarters). Abnormal strip cup scores occurred in six pirlimycin-treated cows (9 quarters). Most of the abnormal udder and strip cup observations were seen in quarters where bacteria were also isolated. Comboutative data from field studies and field use reports indicate that although intramammary infusion of pirlimycin hydrochloride at 50 mg/quarter administered from two to eight consecutive days was well tolerated, repeated infusion with pirlimycin increases the potential for intramammary infections and subsequent clinical mastitis due to environmental bacteria, including coliform bacteria. Adverse reactions, including clinical signs of mastitis (udder swelling and abnormal milk), increased SCIs, and death from coliform mastitis are reported in cows following extended therapy with pirlimycin. Some, but not all, adverse reactions were associated with failure to thoroughly clean quarters and to use aseptic infusion technique.

**Table 1. CLSI-Accepted Interpretive Criteria for Pirlimycin Against Bovine Mastitis Pathogens***

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Disk Potency</th>
<th>Zone Diameter (mm)</th>
<th>MIC Breakpoint (µg/mL)</th>
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<td>Staphylococcus aureus</td>
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* These interpretive criteria are only intended for use when CLSI M31-A2 performance standards are used to determine antimicrobial susceptibility.

**EFFECT ON MILK MANUFACTURING**

A study was conducted to examine the effect of varying concentrations of pirlimycin in milk on the growth of bacterial starter cultures used to produce fermented milk products. Pirlimycin did not adversely affect bacterial starter cultures used for the production of fermented milk products at concentrations found following normal label use including proper milk discard periods. Viable levels of pirlimycin (≤0.40 ppm) can adversely affect the growth of bacterial starter cultures.

**Storage Conditions**

Store at Controlled Room Temperature 20 to 25°C (68 to 77°F). Store Pails in Carton or Pail Until Used.

**HOW SUPPLIED**

PIRSUE Sterile Solution is available in unopened packages of 12-10 mL Plastet Disposable Syringes with 12 individually wrapped 70% isopropanol alcohol pads. The Plastet Disposable Syringes are packaged in Cartons (12-10 mL Plastet Disposable Syringes per carton) and in Pails (12 packages of 12-10 mL Plastet Disposable Syringes or 144 Plastets per pail),

Approved by FDA under NADA # 141-036

**Distributed by**

Zoetis Inc.

Kalamazoo, MI 49007

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