

# ZOETIS OFFERS THE NEWEST MASTITIS TREATMENTS. EVALUATE YOUR OPTIONS.

Brand consistency	<b>SPECTRAMAST® LC</b> (ceftiofur hydrochloride) Sterile Suspension	<b>PIRSUE®</b> (pirlimycin hydrochloride) Sterile Solution	<b>ToDAY®/Cefa-Lak®</b> (cephapirin sodium)	<b>Amoxi-Mast®</b> (amoxicillin)	<b>Dariclox®</b> (sodium cloxacillin)	<b>Hetacin-K®</b> (hetacillin potassium)
Active ingredient	Ceftiofur 125 mg	Pirlimycin 50 mg	Cephapirin 200 mg	Amoxicillin 62.5 mg	Cloxacillin 200 mg	Hetacillin potassium 62.5 mg
Indications	Treatment of clinical mastitis	Treatment of clinical and subclinical mastitis	Treatment of mastitis	Treatment of subclinical mastitis	Treatment of clinical mastitis	Treatment of acute, chronic and subclinical mastitis
Labeled pathogens	<i>Strep dysgalactiae</i> Coagulase-negative staphylococci <i>E. coli</i>	<i>Staph aureus</i> <i>Strep agalactiae</i> <i>Strep dysgalactiae</i> <i>Strep uberis</i>	<i>Strep agalactiae</i> <i>Staph aureus</i>	<i>Strep agalactiae</i> <i>Staph aureus</i>	<i>Strep agalactiae</i> <i>Staph aureus</i>	<i>Strep agalactiae</i> <i>Strep dysgalactiae</i> <i>Staph aureus</i> <i>E. coli</i>
Treatment/ dosing	2-8 treatments 24-hour interval	2-8 treatments 24-hour interval	2 treatments 12-hour interval	3 treatments 12-hour interval	3 treatments 12-hour interval	3 treatments 24-hour interval
Pre-slaughter withdrawal*	2 days	9 days following 2 infusions; 21 days following greater than 2 infusions	4 days	12 days	10 days	10 days
Milk discard*	72 hours	36 hours	96 hours	60 hours	48 hours	72 hours
Availability	R <sub>x</sub>	R <sub>x</sub>	OTC	R <sub>x</sub>	R <sub>x</sub>	R <sub>x</sub>
Extended therapy	Yes	Yes	No	No	No	No

\*After last administration (or treatment)



## KEY FEATURES:

- Treats *E. coli* and other major mastitis pathogens
- Once-a-day dosing — convenient for you, convenient for your milking crew
- 72-hour milk discard — residue trials show that no matter how many days you decide to treat per label directions, milk is safe for human consumption after 72 hours post-last treatment
- Two-day pre-slaughter meat withdrawal — the shortest withhold time available provides more options for greater management flexibility
- Extended therapy — its unique flexible label allows you to treat for 2 to up to 8 days to achieve a bacteriological cure

**Important Safety Information:** Inappropriate dosage or treatment intervals for SPECTRAMAST LC or failure to adhere to proper milk discard period will result in violative milk residues. SPECTRAMAST LC should not be used in animals found to be hypersensitive to the product.



## KEY FEATURES:

- Only lactating product for *Strep uberis*
- Unique clinical and subclinical label
- Short, 36-hour milk discard
- Once-per-day dosing
- Extended therapy — its unique flexible label allows you to treat for 2 to up to 8 days to achieve a bacteriological cure

**Important Safety Information:** Inappropriate dosage or treatment intervals for PIRSUE or failure to adhere to proper milk discard or meat withdrawal will result in violative milk or meat residues. As with all intramammary products, aseptic technique is essential. Repeated infusion during extended duration therapy regimens can result in elevated somatic cell counts and/or clinical mastitis, which can result in animal death. If acute clinical mastitis or other clinical signs of illness develop, discontinue therapy immediately and contact your veterinarian.

# SPECTRAMAST<sup>®</sup> LC

## brand of ceftiofur hydrochloride sterile suspension

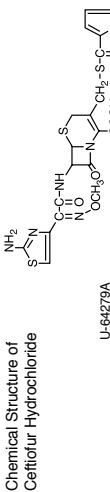
For intramammary infusion in lactating cows only

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

**CAUTION:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION:** Ceftiofur hydrochloride is a cephalosporin antibiotic.

Chemical Structure of Ceftiofur Hydrochloride



**Chemical Name of Ceftiofur Hydrochloride**

5-Thia-1-azabicyclo [4.2.0] oct-2-ene-2-carboxylic acid, 7-[[2-(2-amino-4-thiazolyl)-2-(methoxymino)acetyl]amino]-3-[[2-(2-*is*-lucyl)carbamoyl]thio]methyl]-8-oxo-, hydrochloride.

SPECTRAMAST<sup>®</sup> LC Sterile Suspension (as is) is a sterile suspension of ceftiofur hydrochloride in sterile, preservative-free, isotonic water. Each 10 mL PLASTET<sup>™</sup> Disposable Syringe contains:

Ceftiofur Equivalents (as the hydrochloride salt) ..... 125 mg

Microcrystalline Wax ..... 700 mg

Labralin M 19444 CS ..... 500 mg

Cottonseed Oil ..... q.s.

**INDICATIONS FOR USE**

**SPECTRAMAST<sup>®</sup> LC** (ceftiofur hydrochloride) Sterile Suspension is indicated for the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*. Cows with systemic clinical signs caused by mastitis should receive other appropriate therapy under the direction of a licensed veterinarian.

**DOSSAGE**

Infuse one (1) syringe into each affected quarter. Repeat this treatment in 24 hours. For extended duration therapy, once daily treatment may be repeated for up to 8 consecutive days.

**DIRECTIONS FOR USING THE PLASTET<sup>™</sup> DISPOSABLE SYRINGE**

The 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 Eberhart RJ et al., 1987.

Current Concepts of Bovine Mastitis, 3rd Edition, National Mastitis Council, Arlington, VA.

**a. Full insertion:** Remove the red end cap by pulling straight up as shown. Gently insert the full cannula into the teat canal; carefully insert the product.

**b. Partial insertion:** Remove the red end cap by pulling straight up as shown. Gently insert the full cannula into the teat canal; carefully insert the product.

**Partial Insertion:** Remove the red end cap by pulling straight up as shown. Gently insert the full cannula into the teat canal; carefully insert the product.

**Full Insertion:** Remove the red end cap by pulling straight up as shown. Gently insert the full cannula into the teat canal; carefully insert the product.

**Discard Empty Container: DO NOT REUSE**

**KEEP OUT OF REACH OF CHILDREN**

**ADMINISTRATION**

**Treatment:** Wash teats thoroughly with warm water containing a suitable dairy antiseptic. Dry teats thoroughly. Milk out udder completely. Using an alcohol pad provided, wipe off the end of the affected teat using a separate pad for each teat. Choose the desired insertion length (full or partial) and insert tip into teat canal; push plunger to dispense entire contents, massage the quarter to distribute the suspension into the milk cistern.

**Reinfection:** After successful treatment, reinfection may occur unless good herd management, sanitation, and mechanical safety measures are practiced. Affected cows should be watched carefully to detect recurrence of infection and possible spread to other animals.

**CONTRAINDICATIONS**

As with all drugs, the use of SPECTRAMAST<sup>®</sup> LC Sterile Suspension is contraindicated in animals previously found to be hypersensitive to the drug.

**WARNINGS**

Penicillins and cephalosporins can cause allergic reactions in sensitized individuals. Topical exposures to such antimicrobials, including this product, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact of the product with the skin, eyes, mouth and clothing. Sensitization of the skin may be avoided by wearing latex gloves.

Persons with a known hypersensitivity to penicillin or cephalosporins should avoid exposure to this product.

In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. If allergic reaction occurs (e.g., skin rash, hives, difficulty breathing), seek medical attention.

The material safety data sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information or to obtain a material safety data sheet, call 1-800-366-5288.

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In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. If allergic reaction occurs (e.g., skin rash, hives, difficulty breathing), seek medical attention.

The material safety data sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information or to obtain a material safety data sheet, call 1-800-366-5288.

## EFFECTIVENESS

In 1999 to 2000, the efficacy of ceftiofur was demonstrated in a pivotal multi-location field trial in lactating dairy cattle with clinical mastitis in one quarter. Ceftiofur was formulated in stable cottonseed oil sterile suspension manufactured under GMP guidelines. Cows with mastitis were enrolled in the study if visually abnormal milk (clots, flakes, or watery secretion) or if udder swelling, heat, pain or redness were present and the milk was not yet visually abnormal but California Mastitis Test (CMT) gave results of 2 or greater. A total of 13 trial sites enrolled 352 cows in the study. Cows were assigned to one of three treatment groups: non-treated control, 62.5 mg ceftiofur, and 125 mg ceftiofur. Each treatment group received an intramammary infusion twice at a 24-hour interval in the affected quarter.

Three different definitions for cure were used for analysis purposes: 1) a clinical cure was defined as the milk and udder returning to normal 14 days after the last treatment and remaining normal at the 21-day time point; 2) a bacterial cure was defined as the absence of the pre-treatment pathogen at 14 and 21 days post-treatment; 3) a protocol cure was defined as the absence of the pre-treatment pathogen at 14 and 21 days post-treatment and return to normal of the milk and udder 14 days after the last treatment and remaining normal at the 21-day time point. Three hundred and thirty-seven cows were analyzed for clinical cure rates, which were 54.7% (64/117) for the non-treated control group compared to 68.4% (75/108) for the 62.5 mg treatment group and 78.6% (88/112) for the 125 mg treatment group. The 125 mg treatment groups' clinical cure rate was significantly greater than the non-treated control ( $P=0.002$ ). One hundred and forty-six cows were analyzed for bacterial cure rates, which were 41.3% (19/46) for the non-treated control group, 45.6% (21/46) for the 62.5 mg treatment group and 70.4% (38/54) for the 125 mg treatment group. The 125 mg treatment group's bacterial cure rate was significantly greater than the non-treated control group ( $P=0.006$ ). One hundred and forty-six cows were analyzed for protocol cure rates, which were 63.0% (34/54) for the 125 mg treatment group, 41.3% (19/46) for the 62.5 mg treatment group and 23.9% (11/46) for the non-treated control group. The 125 mg treatment group's protocol cure rate was significantly better than the non-treated control ( $P<0.001$ ) for treatment of clinical mastitis. Thus, 125 mg of ceftiofur administered via intramammary infusion twice at a 24-hour interval was effective in the treatment of clinical mastitis in lactating dairy cows associated with coagulase-negative staphylococci, (*CNS*), *Streptococcus dysgalactiae*, and *Escherichia coli*.

## ANIMAL SAFETY

A pivotal GLP udder irritation study was conducted in 40 cows to assess udder irritation following daily intramammary infusion of an oil-based suspension containing 125 mg of ceftiofur for up to 8 consecutive days. A transient and clinically insignificant rise in SCC to levels <200,000 cells/mL was observed following infusion in normal cows with very low pre-infusion SCC (<10,000 cells/mL). This elevation is not unexpected with oil-based suspensions. The duration of therapy did not affect this elevation. No udder clinical signs of irritation (swelling, pain, or redness), changes in body temperature or in milk production were noted during this study. This pivotal GLP study demonstrated that this formulation is clinically safe and non-irritating to the udder of lactating dairy cows. In two clinical field efficacy studies in 971 lactating dairy cows, no reports of udder irritation or adverse events were noted following infusion. Collectively, these three studies demonstrate that the intramammary infusion of an oil-based suspension containing 125 mg of ceftiofur once daily into all four quarters for up to 8 consecutive days is clinically safe and non-irritating to the udder of lactating dairy cows.

## MILK AND TISSUE RESIDUE DEPLETION

A metabolite study in cattle using radiolabeled ceftiofur provided the data to establish tolerances for ceftiofur-related residues (as desbutyryl-ceftiofur) in tissue and milk. These tolerances are 0.1 ppm in milk, 0.4 ppm in kidney, 2.0 ppm in liver and 1.0 ppm in muscle.

Two pivotal milk residue decline studies were conducted. In these studies, non-mastitic cows received 125 mg of ceftiofur per quarter into all four quarters either twice at a 24-hour interval or once daily for 8 consecutive days. Regardless of treatment duration and using a tolerance of 0.10 ppm for ceftiofur-related residues in milk, these studies demonstrate that milk taken during treatment (a maximum of 8 consecutive daily infusions) and for 72 hours after the last treatment must not be used for human consumption and must be discarded.

A pivotal tissue residue decline study in lactating dairy cattle provided tissue residue decline data. In this study, the cattle received an intramammary infusion of 125 mg of ceftiofur hydrochloride into each of four quarters once daily for 8 consecutive days. Ceftiofur residues were determined in the kidney (the target tissue) using the official analytical method. Kidney residues were less than the established tolerance (0.4 ppm) by 2 days after the last infusion. These data collectively support the assignment of a 2-day pre-slaughter withdrawal period regardless of treatment duration.

**STORAGE CONDITIONS**

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) (See USP). Protect from light. Store plastrats in carton until used.

## HOW SUPPLIED


**SPECTRAMAST<sup>®</sup> LC** Sterile Suspension is available in cartons containing one (1) unbroken package of 12-10 mL PLASTET<sup>™</sup> Disposable Syringes with 12 individually wrapped 70% isopropyl alcohol pads and in pallets containing 12 unbroken packages of 12-10 mL PLASTET<sup>™</sup> Disposable Syringes with 144 individually wrapped 70% isopropyl alcohol pads.


**NADA# 141-238, Approved by FDA**

www.spectramast.com or call 1-800-733-5500

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Revised May 2006

 Distributed by:  
**Pfizer Animal Health**  
Division of Pfizer Inc., NY, NY 10017

 **RESIDUE-FREE**  
MADE IN FRANCE.

# PIRSUE<sup>®</sup> Sterile Solution

(pirfimycin hydrochloride)

For intramammary infusion in lactating cows only

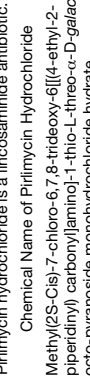
**FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE**

**CAUTION:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

## DESCRIPTION

Pirfimycin hydrochloride is a lincosaminide antibiotic.

Chemical Name of Pirfimycin Hydrochloride



Each 10 mL PLASTET<sup>™</sup> Disposable Syringe contains:

Pirfimycin free base equivalents ..... 50 mg

Aqueous vehicle ..... q.s.

## INDICATIONS FOR USE

PIRSUE Sterile Solution (pirfimycin hydrochloride) is indicated for the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus aureus* and *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

## DOSSAGE

Infuse one (1) syringe into each affected quarter. Use proper teat end preparation and sanitation and proper intramammary infusion technique (see ADMINISTRATION). Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

## ADMINISTRATION

**Teat End Preparation:** Wash teats thoroughly with water containing a suitable dairy antiseptic. 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 part of aseptic infusion technique.

**Important Considerations for Extended Therapy:** For extended duration of therapy, infuse only quarters known to be infected with teat pathogens. Do not constructively, then infuse PIRSUE Sterile Solution using aseptic infusion technique and partial insertion (see diagram below).

**Infusion:** The Plaster 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 Eberhart, R.J., et al., 1987.

Current Concepts of Bovine Mastitis, 3rd Edition, National Mastitis Council, Arlington, VA.

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

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

Choose the desired insertion length (full or partial) and gently insert the tip into the teat canal. Carefully push the plunger to insert the entire contents, and then massage the quarter to distribute the solution into the milk cistern.

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.

**Reinfection:** After treatment, reinfection may occur unless good herd management, sanitation, and mechanical safety measures are practiced. Affected cows should be watched carefully to detect recurrence and possible spread of infection to other animals.

**WARNING**

Repeated infusion during extended duration therapy regimens, even with adequate teat end preparation and sanitation, can result in elevated somatic cell counts and/or clinical mastitis, which can result in animal death. If acute clinical mastitis or other clinical signs of illness develop during extended duration therapy with PIRSUE, discontinue therapy immediately and contact your veterinarian.

**Discard Empty Container: DO NOT REUSE**

**KEEP OUT OF REACH OF CHILDREN**

**RESIDUE WARNINGS**

1. Milk taken from animals during treatment and for 36 hours after the last treatment must not be used for food regardless of treatment duration.

2. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days.

3. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days.

4. Use of this product in a manner other than indicated under DOSAGE might result in violative residues.

Utilizing data that included isolates from cows with mastitis, zone diameter interpretive criteria and minimum inhibitory concentration (MIC) breakpoints were determined using standardized procedures from the Clinical and Laboratory Standards Institute (CLSI), formerly National Committee on Clinical Laboratory Standards M31-A2. The CLSI-accepted interpretive criteria for pirfimycin against Gram-positive mastitis pathogens are shown in Table 1.

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

Pathogen	Disk Potency	Zone Diameter Interpretive Standards (mm)		MIC Breakpoint (µg/mL)
		Susceptible	Resistant	
<i>Staphylococcus aureus</i>	2 µg	≥13	≤12	≤2.0
<i>Streptococcus agalactiae</i>				≥4.0
<i>Streptococcus dysgalactiae</i>				

\*These interpretive criteria are only intended for use when CLSI M31-A2 performance standards are used to determine antimicrobial susceptibility.

## EFFECTIVENESS

The effectiveness of pirfimycin 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 pathogen isolated or the pre-treatment somatic cell count. Cows were treated in the affected quarter(s) with 50, 100, or 200 mg of pirfimycin 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 pathogen 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 enrolled quarters in that cow were cured. All 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 pirfimycin 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 pivotal studies addressing the safety of pirfimycin 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 pirfimycin 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 pirfimycin 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 pirfimycin-treated quarters (82%) in 15 cows had increased SCCs (>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. Udder irritation occurred in seven pirfimycin-treated cows (10 quarters). Abnormal strip cup scores occurred in six pirfimycin-treated cows (9 quarters). Most of the abnormal udder and strip cup observations were seen in quarters where bacteria were also isolated.

Corroborative data from field studies and field use reports indicate that although intramammary infusion of pirfimycin hydrochloride at 50 mg/quarter administered from two to eight consecutive days was well tolerated, repeated infusion with pirfimycin 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 SCCs, and death from coliform mastitis have been reported in cows following extended therapy with pirfimycin. Some, but not all, adverse reactions were associated with failure to thoroughly clean quarters and to use aseptic infusion technique.

## MILK AND TISSUE RESIDUE DEPLETION

The established tolerance of pirfimycin in milk is 0.40 ppm. Milk residue depletion studies were conducted in cows with clinical mastitis. In one study, cows were infused with 50 mg of pirfimycin twice at a 24-hour interval into all quarters regardless of the number of affected quarters. In a second study, cows with a single mastitic quarter were infused with 50 mg of pirfimycin twice at a 24-hour interval into only the affected quarter. In a third study, normal cows were infused with 50 mg of pirfimycin twice at a 24-hour interval into all four quarters. As a result of these three studies, milk taken from cows during treatment and for 36 hours following treatment must not be used for food and must be discarded. For extended duration of therapy (once daily for up to 8 consecutive days), a milk residue study was conducted where cows received 50 mg of pirfimycin per quarter into all four quarters for 8 consecutive days. This study confirmed that milk taken from cows during treatment and for 36 hours following the last treatment must not be used for food and must be discarded.

The established tolerance for pirfimycin in liver (the target tissue) is 0.5 ppm. A pivotal tissue residue study was conducted following administration of 50 mg of pirfimycin twice at a 24-hour interval into all four quarters. Following receipt of the 50 mg of pirfimycin twice at a 24-hour interval into all four quarters, the liver residue decline data from this study supports a 9-day pre-slaughter withdrawal period.

For extended duration of therapy, a second tissue residue study was conducted. Each lactating cow received 50 mg pirfimycin per quarter into all four quarters, once daily for 8 consecutive days. Using the established tolerance for pirfimycin of 0.5 ppm in the liver, these data support a 21-day pre-slaughter withdrawal period for extended duration pirfimycin therapy. Extended duration of therapy is considered as any treatment period longer than 2 days (up to 8 consecutive days) of therapy.

## EFFECT ON MILK MANUFACTURING STARTER CULTURES

A study was conducted to examine the effect of varying concentrations of pirfimycin in milk on the growth of bacterial starter cultures used to produce fermented milk products. Pirfimycin 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. Volatile levels of pirfimycin (>0.40 ppm) can adversely impact the growth of bacterial starter cultures.

## STORAGE CONDITIONS

Store at controlled room temperature 20° to 25° C (68° to 77° F). Store plastrats in carton or pall until used.

## HOW SUPPLIED

PIRSUE Sterile Solution is available in unbroken packages of 12-10 mL Plaster Disposable Syringes with 12 individually wrapped 70% isopropyl alcohol pads. The Plaster Disposable Syringes are packaged in Cartons (12-10 mL Plaster Disposable Syringes per carton) and in Pallets (12 packages of 12-10 mL Plaster Disposable Syringes or 144 Plasters per pallet).

**NADA #141-036, Approved by FDA**

Pharmacia & Upjohn Company  
Division of Pfizer Inc.  
NY, NY 10017



Revised February 2008

# PIRSUE<sup>®</sup> Sterile Solution

(pirfimycin hydrochloride)

For intramammary infusion in lactating cows only

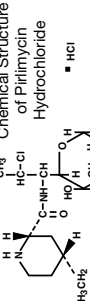
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Pirfimycin hydrochloride is a lincosaminide antibiotic.

Chemical Name of Pirfimycin Hydrochloride



Each 10 mL PLASTET<sup>™</sup> Disposable Syringe contains:

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Aqueous vehicle ..... q.s.

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## ADMINISTRATION

**Teat End Preparation:** Wash teats thoroughly with water containing a suitable dairy antiseptic. 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 part of aseptic infusion technique.

**Important Considerations for Extended Therapy:** For extended duration of therapy, infuse only quarters known to be infected with teat pathogens. Do not constructively, then infuse PIRSUE Sterile Solution using aseptic infusion technique and partial insertion (see diagram below).

**Infusion:** The Plaster 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 Eberhart, R.J., et al., 1987.

Current Concepts of Bovine Mastitis, 3rd Edition, National Mastitis Council, Arlington, VA.

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Choose the desired insertion length (full or partial) and gently insert the tip into the teat canal. Carefully push the plunger to insert the entire contents, and then massage the quarter to distribute the solution into the milk cistern.

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.

**Reinfection:** After treatment, reinfection may occur unless good herd management, sanitation, and mechanical safety measures are practiced. Affected cows should be watched carefully to detect recurrence and possible spread of infection to other animals.

**WARNING**

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