Pirsue® Sterile Solution
(pirlimycin hydrochloride)

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
Pirlimycin hydrochloride is a lincosamide antibiotic.

Chemical Structure of Pirlimycin Hydrochloride

Redacted...

Indications for Use

Anhydrous citric acid
Sodium citrate

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Anhydrous citric acid
Sodium citrate

ADMINISTRATION

For Intramammary Infusion in Lactating Cows Only

Using standardized procedures from the Clinical and Laboratory Standards Institute (CLSI), minimal inhibitory concentration (MIC) breakpoints were determined for pirlimycin and selected Gram-positive and Gram-negative environmental pathogens. For a complete listing of adverse reactions for pirlimycin reported to the Center for Veterinary Medicine (CVM) see http://www.fda.gov/cvm/ade_cum.htm. For technical assistance, to report suspected adverse reactions, or to request a Safety Data Sheet (SDS), call 1-888-963-8471.

Microbiology

Pirlimycin is a lincosamide antibiotic that has activity against Gram-positive mastitis pathogens. Pirlimycin functions via binding to the 1,0-kb subunit of bacterial ribosomes. In vitro activity of pirlimycin has been demonstrated against Staphylococcus aureus, Streptococcus agalactiae, and Staphylococcus ubiquis, four pathogens associated with clinical and subclinical mastitis in lactating dairy cows. Utilizing data that included isolates from cows with mastitis, zone diameter interpretive criteria and minimum inhibitory concentration (MIC) breakpoints were calculated using standardized procedures from the Clinical and Laboratory Standards Institute (CLSI) and the National Committee of Clinical Laboratory Standards (M3-A2). The CLSI-accepted interpretive criteria for pirlimycin-resistant Gram-positive mastitis pathogens are shown in Table 1.
MILK AND TISSUE RESIDUE DEPLETION

The established tolerance of pirlimycin in milk is 0.05 ppm. Milk residue depletion studies were conducted in cows with clinical mastitis. In one study, cows were infused with 50 mg of pirlimycin 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 pirlimycin twice at a 24-hour interval into the affected quarter. In a third study, normal cows were infused with 50 mg of pirlimycin 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 pirlimycin 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 pirlimycin in liver (the target tissue) is 0.15 ppm. A pivotal tissue residue study was conducted following administration of 50 mg of pirlimycin twice at a 24-hour interval into all four quarters. Following receipt of the 50 mg of pirlimycin 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 pirlimycin per quarter into all four quarters, once daily for 8 consecutive days. Using the established tolerance for pirlimycin of 0.5 ppm in the liver, these data support a 21-day pre-slaughter withdrawal period for extended duration pirlimycin therapy. Extended duration of therapy is considered as any treatment period longer than 2 days (e.g., 11-day, 36-day).

EFFECT ON MILK MANUFACTURING

STARTER CULTURES

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. The established tolerance 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 Plastet's in Cartons or Pails. Plastet's in Cartons are intended for use in Pails (13 packages of 12-10 mL Plastet Disposable Syringes or 144 Plastets per pail).

HOW SUPPLIED

Plastet Disposable Solution is available in unbroken packages of 12-10 mL Plastet Disposable Syringes with 13 individually wrapped 75% isopropanol loaded tips.

The Plastet Disposable Syringes are packaged in Cartons in Pails, 13 packages of 12-10 mL Plastet Disposable Syringes or 144 Plastets per pail.

Plastet Disposable Solution is approved by FDA 12654402

Manufactured by: Northbrooke Laboratories Ltd.
Niexy, Northern Ireland, UK

Made in the United Kingdom

zqetis

Global External Supply

Date: 21 Oct 2016
Time: 07:52

Description
Artwork Code
Component
Leafflet
Norbrook
045
Pharma Code
0TIN
N/A
Market
USA
Perigord Nº
293602
Colours
Black

Proof

SKU N°

N/A

Tel: +353 (0) 1 440 3222
Web: www.perigord-as.com
E-mail: PerigordZoetis@perigord-as.com

TEXT SIZE

The BODY text on this A/W is at:

6.0 pt

Dimensions
110 x 216 mm
Drawing Number N/A

Xref