

**PART 526—INTRAMAMMARY  
DOSAGE FORMS**

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AUTHORITY: 21 U.S.C. 360b.

**§ 526.88 Amoxicillin trihydrate for intramammary infusion.**

(a) *Specifications.* Each single dose syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams of amoxicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use—Lactating cows—*(1) *Amount.* One syringe (equivalent to 62.5 milligrams amoxicillin) per quarter.

(2) *Indications for use.* For the treatment of subclinical infectious bovine mastitis due to *Streptococcus agalactiae* and *Staphylococcus aureus* (penicillin sensitive).

(3) *Limitations.* Administer after milking. Clean and disinfect the teat. Use one syringe per infected quarter every 12 hours for a maximum of 3 doses. Do not use milk taken from

treated animals for food purposes within 60 hours (5 milkings) after last treatment. Do not slaughter treated animals for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

**§ 526.363 Cephapirin benzathine.**

(a) *Specifications.* Each 10 milliliter disposable syringe contains 300 milligrams of cephapirin activity (as cephapirin benzathine) in a peanut-oil gel.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use—*(1) *Amount.* Infuse contents of one syringe into each infected quarter.

(2) *Indications for use.* Use in dry cows for treatment of mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*.

(3) *Limitations.* Infuse each infected quarter following last milking or early in the dry period, but no later than 30 days before calving. Milk from treated cows must not be use for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until 42 days after the latest infusion. For use in dry cows only.

[43 FR 37174, Aug. 22, 1978, as amended at 53 FR 27851, July 25, 1988]

**§ 526.365 Cephapirin sodium for intramammary infusion.**

(a) *Specifications.* Each 10-milliliter dose contains 200 milligrams of cephapirin sodium activity in a peanut-oil gel.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use.* (1) The drug is used for the treatment of lactating cows having bovine mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*.

(2) Administer one dose into each infected quarter immediately after the quarter has been completely milked

out. Do not milk out for 12 hours. Repeat once only in 12 hours. If improvement is not noted within 48 hours after treatment, consult your veterinarian.

(3) Milk that has been taken from animals during treatment and for 96 hours (8 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment.

[40 FR 57455, Dec. 10, 1975, as amended at 53 FR 27852, July 25, 1988. Redesignated at 63 FR 8349, Feb. 19, 1998]

**§ 526.464 Cloxacillin intramammary dosage forms.**

**§ 526.464a Cloxacillin benzathine for intramammary infusion.**

(a) *Specifications.* Each dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter for use in dairy cows.

(1) *Amount.* Administer aseptically into each infected quarter immediately after last milking or early in dry period.

(2) *Indications for use.* Treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* including penicillin resistant strains in dairy cows during the dry period.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Animals infused with this product must not be slaughtered for food use for 30 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter for use in dairy cows.

(1) *Amount.* Administer one dose in each quarter immediately after last milking.

(2) *Indications for use.* Treatment and prophylaxis of bovine mastitis in non-lactating cows due to *S. agalactiae* and *S. aureus*.

(3) *Limitations.* For use in dry cows only. Not to be used within 4 weeks (28 days) of calving. Animals infused with this product must not be slaughtered

for food use for 4 weeks (28 days) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

**§ 526.464b Cloxacillin benzathine for intramammary infusion, sterile.**

(a) *Specifications.* Each 6 milliliter dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(1) *Amount.* 6 milliliters per infected quarter aseptically immediately after last milking at the time of drying-off of the cow.

(2) *Indications for use.* Treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* in dairy cows at the time of drying-off of the cow.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Milk taken from treated cows prior to 72 hours (6 milkings) after calving must not be used for human food. Animals infused with this product must not be slaughtered for food from the time of infusion until 72 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(1) *Amount.* One dose per infected quarter immediately after last milking.

(2) *Indications for use.* Treatment and prophylaxis of bovine mastitis in non-lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*.

(3) *Limitations.* For use in dry cows only. Not to be used within 4 weeks (28 days) of calving. Animals infused with this product must not be slaughtered for food use for 4 weeks (28 days) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55660, Nov. 2, 1995]