PART 526—INTRAMAMMARY DOSAGE FORMS

§ 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.

§ 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...
§ 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.

(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 in dairy cows during the dry period.

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

(4) Amount. Administer one dose per infected quarter immediately after last milking.

(2) Indications for use. Treatment and prophylaxis of bovine mastitis in nonlactating 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) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 526.464c Cloxacillin sodium for intramammary infusion, sterile.

(a) Specifications. Each milliliter contains cloxacillin sodium equivalent to 20.0 milligrams of cloxacillin.

(b) Sponsor. See No. 00069 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.165 of this chapter.

(d) Conditions of use. Lactating cows—
(1) Amount. 10 milliliters (one dose of 200 milligrams) per infected quarter.
(2) Indications for use. Treatment of mastitis in lactating cows due to Staphylococcus agalactiae and Staphylococcus aureus, nonpenicillinase-producing strains.
(3) Limitations. Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (four milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

§ 526.1130 Hetacillin potassium for intramammary infusion.

(a) Specifications. Each 10 milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams of ampicillin.
(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.
(c) Conditions of use. Lactating cows—

(1) Amount. 10 milliliters of hetacillin potassium equivalent to 62.5 milligrams ampicillin into each infected quarter. Repeat at 24-hour intervals until a maximum of three treatments has been given.

(2) Indications for use. Treating acute, chronic, or subclinical bovine mastitis in lactating cows caused by susceptible strains of Streptococcus agalactiae, Streptococcus dysgalactiae, Staphylococcus aureus, and Escherichia coli.

(3) Limitations. If definite improvement is not noted within 48 hours after treatment, the causal organism should be further investigated. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food use for 10 days following latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 526.1590 Novobiocin oil suspension.

(a)(1) Specifications. Each 10 milliliters of oil suspension contains the equivalent of 400 milligrams of novobiocin (present as sodium novobiocin).

(2) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(3) Related tolerances. See §556.460 of this chapter.

(4) Conditions of use—(i) Amount. Infuse 10 milliliters (equivalent to 150 milligrams of novobiocin) in each quarter after milking. Repeat treatment once after 24 hours.

(ii) Indications for use. Use in lactating cows for treatment of mastitis caused by susceptible strains of Staphylococcus aureus.

(iii) Limitations. Do not milk for at least 6 hours after treatment; afterwards, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after latest treatment must not be used for food. Do not slaughter treated animals for food for 30 days following latest treatment. If redness, swelling, or abnormal milk persists or increases after treatment, discontinue use and consult a veterinarian. For udder instillation in lactating cattle only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992]

§ 526.1696 Penicillin intramammary dosage forms.

§ 526.1696a Penicillin G procaine in oil.

(a) Specifications. Each milliliter contains penicillin G procaine equivalent to 100,000 units of penicillin G in peanut, sesame, or soybean oils.

(b) Related tolerances. See §556.510 of this chapter.

(c) Sponsor. See No. 010515 in §510.600(c) of this chapter.

(1) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions specified in paragraph (c)(2)(i)(B) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(2) Conditions of use. Treating bovine mastitis caused by Streptococcus agalactiae, S. dysgalactiae, and St. uber in lactating cows as follows:

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(i) Three-dose regimen. Administer by intramammary infusion in each infected quarter as follows:

(A) 6-milliliter dose (peanut oil). Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 84 hours (7 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 4 days after the latest treatment.

(B) 10-milliliter dose (sesame oil). Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(ii) Two-dose regimen. 10-milliliter dose (peanut oil). Administer by intramammary infusion in each infected quarter. Treatment may be repeated at intervals of 12 hours. Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(d) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(1) 10-milliliter dose (peanut oil). Administer by intramammary infusion in each infected quarter. Treatment may be repeated at 12-hour intervals for not more than three doses, as indicated by clinical response.

(2) Indications for use. Treating bovine mastitis caused by Streptococcus agalactiae, S. dysgalactiae, and S. uberis in lactating cows as follows:

(3) Limitations. Milk that has been taken from animals during treatment and for 60 hours after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(e) Sponsor. See No. 010515 (sesame oil) and No. 050604 (peanut oil) in §510.600(c) of this chapter.

(1) NAS/NRC status. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalence and safety information.

(2) Single-dose regimen. One 10-milliliter dose (sesame oil or peanut oil) in each infected quarter at time of drying off.

(3) Indications for use. Treating bovine mastitis caused by Streptococcus agalactiae in dry cows.

(4) Limitations. Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk. Animals must not be slaughtered for food within 14 days postinfusion.

[57 FR 37335, Aug. 18, 1992, as amended at 58 FR 500, Jan. 6, 1993]

§ 526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

(a) Specifications. Each 10 milliliters of suspension contains penicillin G procaine equivalent to 200,000 units of penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams of dihydrostreptomycin.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) Related tolerances. See §§556.200 and 556.510 of this chapter.

(d) Conditions of use. Dairy cows—(1) Amount. One syringe into each quarter at the last milking prior to drying off.

(2) Indications for use. Intramammary treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by Staphylococcus aureus and Streptococcus agalactiae.

(3) Limitations. Not to be used within 6 weeks of calving. For use in dry cows only. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment nor within 24 hours after calving.

[57 FR 37336, Aug. 18, 1992]

§ 526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

(a) Specifications. Each 10 milliliters of suspension contains penicillin G procaine equivalent to 1 million units of penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram of dihydrostreptomycin.
§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

(a) Specifications. For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Lactating cows—(i) Amount. 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.
(2) Indications for use. Treating lactating cows for mastitis caused by susceptible strains of Staphylococcus aureus; Streptococcus agalactiae, Strep. dysgalactiae; and Streptococcus uberis.
(3) Limitations. For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 36 hours following the last treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

(2) Dry cows—(i) Amount. 10 milliliters in each quarter at time of drying off.
(2) Indications for use. Treatment of subclinical mastitis caused by susceptible strains of Staphylococcus aureus and Streptococcus agalactiae.
(3) Limitations. For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]