Food and Drug Administration, HHS

§ 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.

(4) Sponsor. See No. 000061 in §510.600(c) of this chapter.
(5) Related tolerances. See §556.165 of this chapter.
(6) 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 *Streptococcus 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 (4 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.

§ 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. 000061 in §510.600(c) of this chapter.
(c) Related tolerances. See §556.165 of this chapter.
(d) Conditions for use. Lactating cows—
(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 30 days of calving. 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.

(4) Sponsor. See No. 000069 in §510.600(c) of this chapter.
(5) Related tolerances. See §556.165 of this chapter.
(6) Conditions for 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 *Streptococcus 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 (4 milkings) after the latest treatment should not be used for food.
§ 526.820 Erythromycin.

(a) Specifications. (1) Each 6-milliliter, single-dose, disposable syringe contains 300 milligrams of erythromycin (as the base), 0.45 milligram of butylated hydroxyanisole, and 0.45 milligram of butylated hydroxytoluene.

(2) Each 12-milliliter, single-dose, disposable syringe contains 600 milligrams of erythromycin (as the base), 0.90 milligram of butylated hydroxyanisole, and 0.90 milligram of butylated hydroxytoluene.

(3) The vehicle is triglyceride of saturated fatty acids from coconut oil.

(b) Sponsor. See No. 061623 in § 510.600(c) of this chapter.

c) Indications for 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. 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 until 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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. 000010 in § 510.600(c) of this chapter.

c) Indications for use. Lactating cows—

(i) Amount. 10 milliliters of oil suspension contains the equivalent of 400 milligrams of novobiocin (present as sodium novobiocin).

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

(iii) Conditions of use. Treatment of mastitis due to Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, and Streptococcus uberis in lactating or dry cows.

(iv) Limitations. Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food.

§ 526.1590 Novobiocin oil suspension.

(a)(1) Specifications. Each 10 milliliters of oil suspension contains the equivalent of 150 milligrams of novobiocin (present as sodium novobiocin).

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

(iii) Conditions of use. It is used in dry cows for the treatment of mastitis caused by susceptible strains of Staphylococcus aureus and Streptococcus agalactiae.

(iv) Limitations. Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food use for 30 days following udder infusion. For udder installation for the treatment of mastitis in dry cows only.

§ 526.1130 Hetacillin potassium for intramammary infusion.