Food and Drug Administration, HHS

§ 526.363 Cefiofur.

(a) Specifications. Each single-use, 10-milliliter syringe of cefiofur hydrochloride suspension contains 125 milligrams (mg) or 500 mg cefiofur equivalents.

(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

(c) Related tolerances. See § 556.113 of this chapter.

(d) Conditions of use—(1) Lactating cows.—(i) Amount. Infuse 125 mg per affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) Indications for use. For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, Streptococcus dysgalactiae, and Escherichia coli.

(iii) Limitations. Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

(2) Dry cows—(i) Amount. Infuse 500 mg per affected quarter at the time of dry off.

(ii) Indications for use. For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with Staphylococcus aureus, Streptococcus dysgalactiae, and Streptococcus uberis.

(iii) Limitations. Milk taken from cows completing a 30-day dry-off period may be used for food with no milk discard due to cefiofur residues. Following intramammary infusion, a 16-day preslaughter withdrawal period is required for treated cows. Following label use, no preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.


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

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

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

(2) Indications for use. Use in dry cows for treatment of mastitis caused by susceptible strains of Streptococcus agalactiae and Staphylococcus aureus, including penicillin-resistant strains.

(3) Limitations. Infuse each quarter following last milking, but no later than 30 days before calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until