

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

- 529.50 Amikacin sulfate intrauterine solution.
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 529.1044 Gentamicin sulfate in certain other dosage forms.
 529.1044a Gentamicin sulfate intrauterine solution.
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 529.1526 Nifurpirinol capsules.
 529.2090 Salicylic acid.
 529.2464 Ticarcillin powder.
 529.2503 Tricaine methanesulfonate.

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

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§ 529.50 Amikacin sulfate intrauterine solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See No. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares when caused by susceptible organisms including *E. coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations.* For intrauterine infusion in the horse only. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 9640, Mar. 8, 1983, as amended at 53 FR 27852, July 25, 1988; 62 FR 15110, Mar. 31, 1997; 62 FR 23358, Apr. 30, 1997]

§ 529.360 Cephalothin discs.

(a) *Specifications.* Cephalothin discs, comply with the requirements of § 460.1 of this chapter.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The discs are used for determining the in vitro susceptibility of bacteria to cephaloridine and cephalonium.

(2) For veterinary laboratory diagnosis only.

§ 529.400 Chlorhexidine tablets and suspension.

(a) *Specification.* Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.¹

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

(c) *Conditions of use—(1) Amount.* Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.¹

(2) *Indications for use.* For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.¹

(3) *Limitations.* Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.¹

[43 FR 10705, Feb. 23, 1979]

§ 529.1003 Flurogestone acetate-impregnated vaginal sponge.

(a) *Specifications.* Each vaginal sponge contains 20 milligrams of flurogestone acetate.

(b) *Sponsor.* See No. 000014 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For synchronizing estrus/ovulation in cycling adult ewes during their normal breeding season.

(2) *Limitations.* Using applicator provided, insert sponge into ewe's vagina 13 days before desired start of breeding. For intravaginal use in sheep only. Do not use in young ewes that have not

¹These conditions are NAS/NRC reviewed and deemed 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.