§ 520.88 Amoxicillin oral dosage forms.

§ 520.88a Amoxicillin trihydrate film-coated tablets.

(a) Specifications. Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams of amoxicillin.

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

(c) Conditions of use—(1) Dogs—(A) Amount. 5 milligrams per pound of body weight twice daily.

(B) Indications for use. Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis), gastrointestinal tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abcesses, lacerations, wounds) caused by susceptible strains of Staphylococcus aureus, Streptococcus spp., Escherichia coli, Proteus mirabilis, and bacterial dermatitis caused by S. aureus, Streptococcus spp., E. coli, and P. mirabilis; gastrointestinal tract (bacterial gastroenteritis) caused by S. aureus, Streptococcus spp., E. coli, and P. mirabilis; bacterial dermatitis caused by S. aureus, Streptococcus spp., and P. mirabilis; and soft tissues (abcesses, lacerations, and wounds) caused by S. aureus, Streptococcus spp., E. coli, and P. mirabilis.

(C) Limitations. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) Cats—(A) Amount. 50 milligrams (5 to 10 milligrams per pound of body weight) once a day.

(B) Indications for use. Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to S. aureus, Streptococcus spp., and E. coli; genitourinary tract (cystitis) due to S. aureus, Streptococcus spp., E. coli, and P. mirabilis; gastrointestinal tract due to E. coli; and skin and soft tissue (abcesses, lacerations, and wounds) due to S. aureus, Streptococcus spp., E. coli, and Pasteurella multocida.

(iii) Limitations. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) Specifications. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

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

(1) Conditions of use—(i) Dogs—(A) Amount. 5 milligrams per pound of body weight twice daily.

(B) Indications for use. Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by Staphylococcus aureus, Streptococcus spp., Escherichia coli, and Proteus mirabilis; genitourinary tract (cystitis) caused by S. aureus, Streptococcus spp., E. coli, and P. mirabilis; gastrointestinal tract (bacterial gastroenteritis) caused by S. aureus, Streptococcus spp., E. coli, and P. mirabilis; bacterial dermatitis caused by S. aureus, Streptococcus spp., and P. mirabilis; and soft tissues (abcesses, lacerations, and wounds) caused by S. aureus, Streptococcus spp., E. coli, and P. mirabilis.

(C) Limitations. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) Cats—(A) Amount. 50 milligrams (5 to 10 milligrams per pound) once daily.

(B) Indications for use. Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to Staphylococcus spp., Streptococcus spp., Hemophilus spp., E. coli, Pasteurella spp., and P. mirabilis; genitourinary tract (cystitis) due to S. aureus, Streptococcus spp., E. coli, P. mirabilis, and Corynebacterium spp.; gastrointestinal tract due to E. coli, Proteus spp., Staphylococcus spp., and Streptococcus spp.; skin and soft tissue (abcesses, lacerations, and wounds) due to Staphylococcus spp., Streptococcus spp., E. coli, and Pasteurella multocida.
(C) Limitations. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]
(c) Sponsors. See Nos. 000856 and 051311 in § 510.600(c) of this chapter.

(i) Conditions of use. Dogs—(i) Amount. 5 milligrams per pound of body weight twice daily.

(ii) Indications for use. Treatment of bacterial dermatitis due to \textit{S. aureus}, \textit{Staphylococcus spp.}, \textit{Streptococcus spp.}, and \textit{E. coli}, and soft tissue infections (abscesses, wounds, lacerations) due to \textit{S. aureus}, \textit{Streptococcus spp.}, \textit{E. coli}, \textit{P. mirabilis} and \textit{Staphylococcus spp.}

(iii) Limitations. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

§ 520.88d Amoxicillin trihydrate soluble powder.

(a) Specifications. Each gram contains amoxicillin trihydrate equivalent to 115.4 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. Pre-ruminating calves including veal calves—(1) Amount. 400 milligrams per 100 pounds of body weight twice daily.

(2) Indications for use. Treatment of bacterial enteritis when due to susceptible \textit{Escherichia coli} in pre-ruminating calves including veal calves.

(3) Limitations. Administer by drench or by mixing in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. For use in pre-ruminating calves including veal calves only, not for use in other animals which are raised for food production. Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.88e Amoxicillin trihydrate oral suspension.

(a) Specifications. Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin.

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

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

(d) Conditions of use. Swine—(1) Amount. 40 milligrams orally, twice a day using a dosing pump.

(2) Indications for use. Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by \textit{Escherichia coli} susceptible to amoxicillin.

(3) Limitations. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days. Do not slaughter during treatment or for 15 days after latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]