SPECTINOMYCIN (Veterinary—Systemic)

Some commonly used brand names for veterinary-labeled products are: Adspec Sterile Solution; Spectam; Spectam Injectable; Spectam Oral Solution; Spectam Scour-Halt; Spectam Powder; Spectam Water Soluble; Spectam Water Soluble Concentrate; and Spectguard Scour-Chek.

Note: For a listing of dosage forms and brand names by country availability, see the Dosage Forms section(s).

Category: Antimicrobial (systemic).

Indications:
Note: The text between ELUS and ELUS describes uses that are not included in U.S. product labeling. Text between ELUS and ELUS describes uses that are not included in Canadian product labeling.
The ELUS or ELCAN designation can signify a lack of product availability in the country indicated. See the Dosage Forms section of this monograph to confirm availability.

General considerations
Spectinomycin is an antibiotic that is active against a variety of aerobic gram-negative and gram-positive organisms as well as Mycoplasma species. Spectinomycin is used clinically, primarily for its activity against gram-negative organisms; some gram-positive organisms may also be susceptible to this agent. It has in vitro and in vivo activity against Mannheimia (Pasteurella) haemolytica, Pasteurella multocida, and Haemophilus somnus. Anaerobic organisms are generally resistant. Spectinomycin is usually bacteriostatic at therapeutic doses. As an aminocyclitol antibiotic, spectinomycin is structurally and functionally similar to the aminoglycoside antibiotics, which are also aminocyclitols. Spectinomycin lacks the toxic effects of the aminoglycoside antibiotics; however, its use is limited by the ready development of bacterial resistance.

Accepted
Air sacculitis (treatment)
— Turkey pouls, 1- to 3-day-old: Spectinomycin hydrochloride injection is indicated to aid in the control of air sacculitis associated with Mycoplasma meleagridis sensitive to spectinomycin.

Chronic respiratory disease (CRD) (prophylaxis)—Chickens, broiler: Spectinomycin powder for oral solution is indicated to aid in the prevention of mortality due to CRD associated with susceptible Mycoplasma gallisepticum.

Chronic respiratory disease (CRD) (treatment)—
Chickens, broiler: Spectinomycin powder for oral solution is indicated to aid in the control of mortality due to CRD associated with susceptible Mycoplasma gallisepticum.

Turkeys:
— S. gallinarum infection (treatment)3—Spectinomycin injection is indicated to aid in the control of mortality due to S. gallinarum infection in turkeys.

Ducklings:
— Colibacillosis (treatment)3—Spectinomycin injection is indicated to aid in the control of mortality due to coli infection in ducklings.

Potentially effective
— S. gallinarum, chicken: Spectinomycin injection is indicated to aid in the control of mortality due to S. gallinarum infection in chickens.

Infections, oral, viral (treatment)—ELUS
— Pigs: Spectinomycin injection is indicated to aid in the control of mortality associated with viral infections in pigs.

Regulatory Considerations
U.S.—
Spectinomycin is not labeled for use in birds producing eggs for human consumption.

Withdrawal times have been established for the use of spectinomycin in newly hatched broilers, pigs and turkeys (see the Dosage Forms section).

Canada—
Spectinomycin is not labeled for use in birds producing eggs for human consumption.

Spectinomycin injection is not labeled for use in turkeys weighing less than 0.5 kg.

Withdrawal times have been established for the use of spectinomycin in broiler chickens, pigs, and turkeys (see the Dosage Forms section).

Chemistry
Source: Spectinomycin is a product of Streptomyces spectabilis.

Chemical group: Aminocyclitol.

Chemical name:
Spectinomycin hydrochloride—4H-Pyran[2,3-

Chemical name:
Spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-

Spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-

Spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-


dap=spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-

Spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-

Spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-

Spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-

Spectinomycin sulfate tetrahydrate—Decahydrate-4H-Pyran[2,3-
Molecular formula: Spectinomycin hydrochloride—C_{14}H_{24}N_{2}O_{7}·2HCl·5H_{2}O

Molecular weight: Spectinomycin hydrochloride—495.35 g/mol

Description: Spectinomycin Hydrochloride USP—White to pale-buff crystalline powder.

pKa: 6.95 and 8.70

Solubility: Spectinomycin Hydrochloride USP—Freely soluble in water; practically insoluble in alcohol, in chloroform, and in ether.

Pharmacology/Pharmacokinetics

Note: Unless otherwise noted, pharmacokinetic data in this section are based on a single intravenous injection of spectinomycin.

The pharmacokinetics and detection of spectinomycin do not appear to be influenced by administration in combination with lincomycin; some of the pharmacokinetic data in this section are derived from studies in which lincomycin and spectinomycin were administered concomitantly.

Mechanism of action/Effect: Spectinomycin binds to the 3OS ribosomal subunit of the microorganism and inhibits protein synthesis by preventing elongation of the polypeptide chain at the translocation step.

Absorption: Spectinomycin is only slightly absorbed from the gastrointestinal tract; however, it is rapidly absorbed following intramuscular administration. In cattle, spectinomycin is completely bioavailable following intramuscular administration. Repeated administration in cattle does not appear to result in tissue concentrations higher than those achieved with a single dose.

Distribution: Twelve hours following intramuscular administration and 24 hours following oral administration, concentrations of spectinomycin are found in the following swine tissues in decreasing concentrations: kidney, liver, lung, muscle, and fat.

An identical profile is seen in cattle 24 and 72 hours following intramuscular administration of spectinomycin. Tissue: serum ratios of spectinomycin usually do not exceed 0.25 to 0.5 and are much lower in brain, aqueous humor, and bone.

Volume of distribution (Vd): Cows—0.295 L/kg (L/kg). Ewes—0.307 L/kg.

Protein binding: Cows—Low (approximately 10%).

Biotransformation: Spectinomycin does not appear to undergo any significant metabolism. In swine, it is excreted unchanged in the urine following intramuscular administration.

Half-life: Elimination—Cows: 1.01 to 1.2 hours. Ewes: 1.01 hours. Pigs: 0.98 hour.

Peak serum concentration: Calves, preruminating—20 micrograms per mL (mcg/mL) between 0.33 and 0.67 hours following an intramuscular dose of 10 mg per kg of body weight (mg/kg).

Cows—Approximately 55 mcg/mL, at 1 hour following an intramuscular dose of 20 mg/kg.

Dogs—Intramuscular: 78 mcg/mL 40 minutes following an intramuscular dose of 40 mg/kg.

Oral: 22 mcg/mL approximately 4 hours following a dose of 100 mg/kg.

500 mg/kg. Ewes—Approximately 53 mcg/mL at 1 hour following an intramuscular dose of 20 mg/kg.

Elimination: Following intramuscular administration—Spectinomycin is rapidly absorbed, then quickly eliminated from plasma and tissues through renal excretion. Because of this rapid excretion, drug accumulation is not observed following repeated administration. Renal impairment may cause accumulation of the active drug.

Following oral administration—Because spectinomycin is poorly absorbed from the gastrointestinal tract, it is excreted mostly in the feces.

Precautions to Consider

Lactation

Cows: In one experimental study, the milk-to-serum ratio of spectinomycin concentrations ranged from 0.44 to 1.12 in mastitic cows receiving one intramuscular dose of 20 mg per kg of body weight (mg/kg), followed by three intramuscular doses of 10 mg/kg at hourly intervals. Spectinomycin levels in milk from dairy cows receiving an intramuscular dose of 20 mg/kg two times a day for 3 consecutive days were below 0.2 mcg/mL at the fifth milking after the last injection. No residues of spectinomycin were detectable at the seventh milking.

Side/Adverse Effects

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and, for humans, symptoms in parentheses where appropriate)—not necessarily inclusive:

Those indicating need for medical attention

All species

Anaphylactic reactions; neuromuscular blockade

Those indicating need for medical attention only if they continue or are bothersome

Incidence unknown

Cattle

Discoloration of tissue at the injection site; swelling at the injection site, mild

Human side/adverse effects

In addition to the above side/adverse effects reported in animals, the following side/adverse effects have been reported in humans, and are included in the human monograph Spectinomycin (Systemic) in USP DI Volume I; these side/adverse effects are intended for informational purposes only and may or may not be applicable to the use of spectinomycin in the treatment of animals:

Incidence rare

Dizziness; gastrointestinal disturbance; hypersensitivity; pain at site of injection

Overdose

For more information in cases of overdose or unintentional ingestion, contact the American Society for the Prevention of Cruelty to Animals (ASPCA) National Animal Poison Control Center (888-426-4435 or 900-443-0000; a fee may be required for consultation) and/or the drug manufacturer.

Cattle: When cattle were administered 150 mg per kg a day (10 times the labeled dose) for 5 days, the effects seen at the end of the treatment period included increased relative kidney weights. Urinalysis was performed only on steers. Urinary pH was decreased and squamous and transitional cells were found in the urine.
Clinical effects of overdose
Note: The following effects have been selected on the basis of their potential clinical significance (possible signs in parentheses—where appropriate)—not necessarily inclusive (» = major clinical significance):

Acute effects—
* Turkey poults [R-1]

* Ataxia; coma
  Note: Clinical signs of ataxia and coma following a single, subcutaneous injection of up to 50 mg per poult caused no detectable ill effects.

Veterinary Dosing Information
Safety considerations
Some individuals who handle spectinomycin develop serious reactions involving skin, nails, and eyes. Individuals who have experienced a rash or other evidence of allergic reaction should avoid further contact with spectinomycin. [R-2]

Oral Dosage Forms
Note: The dosing and strengths of the dosage forms available are expressed in terms of spectinomycin base (not the hydrochloride salt).


SPECTINOMYCIN HYDROCHLORIDE ORAL SOLUTION
Usual dose: Enteritis, bacterial—Pigs, younger than 4 weeks of age or less than 6.8 kg of body weight:
  For pigs weighing < 4.5 kg—Oral, 50 mg (base) as a total dose per animal two times a day for three to five days. [R-3; 4]
  For pigs weighing 4.5 kg to 6.8 kg—Oral, 100 mg (base) as a total dose per animal two times a day for three to five days. [R-3; 4]
Withdrawal times—US and Canada: Meat—21 days. [R-3; 4]
Note: If improvement is not seen within forty-eight hours of initiating treatment, the diagnosis or choice of therapy should be reconsidered. [R-3; 4]

Strength(s) usually available:
  U.S.—
    For veterinary-labeled product(s):
      50 mg (base) per mL (OTC) [Spectam Scour-Halt; Spectoguard Scour-Chek].
    Canada—
    For veterinary-labeled product(s):
      50 mg (base) per mL (OTC) [Spectam Powder; Spectam Water Soluble Concentrate].

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer.

Preparation of dosage form: Water-soluble powder should be mixed with drinking water according to the manufacturer’s directions.

USP requirements: Not in USP. [R-16]

Parenteral Dosage Forms
Note: The dosing and strengths of the dosage forms available are expressed in terms of spectinomycin base (not the hydrochloride or sulfate salt).


SPECTINOMYCIN HYDROCHLORIDE INJECTION
Usual dose:

* Air sacculitis (treatment)[R-17]—Turkey poultis, 1- to 3-day-old: Subcutaneous in cervical area, 10 mg (base) as a single, total dose per poult. [R-17]
  Withdrawal times—US: Meat—0 days. [R-17]
  —Canada: Meat—21 days. [R-2; 18; 19]

* Chronic respiratory disease (treatment)[R-17]—Turkey poultis, 1- to 3-day-old: Subcutaneous in cervical area, 5 mg (base) as a single, total dose per poult. [R-17]
  Dilution with sterile physiologic saline is recommended to facilitate accurate dosing. [R-17]
  Withdrawal times—US: Meat—0 days. [R-17]

* Colibacillosis (treatment)[R-2; 18; 19]

* Paratyphoid (treatment)[R-2; 18; 19]

* Salmonella infantis infection (treatment)[R-2; 18; 19]

* Synovitis (treatment)[R-17]—Chicks, newly hatched: Subcutaneous in cervical area, 2.5 to 5 mg (base) as a single, total dose per chick. [R-17]
  Dilution with sterile physiologic saline is recommended so that the total volume administered is 0.2 mL. [R-17]
  Withdrawal times—US: Meat—0 days. [R-17]

* Fowl cholera (treatment)[R-17]—Turkeys: Subcutaneous in dorsal
cervical area, 11 to 22 mg (base) per kg of body weight as a single injection. The entire flock should be treated as soon as symptoms of fowl cholera are seen. Treatment must not be repeated within five days of the initial treatment.\(^{[R-4]}\)

**Withdrawal times:** Canada: Meat—5 days.\(^{[R-1]}\)

**Note:** ELUS,CAN

**Note:** It is recommended that this medication be administered intra muscularly in the neck and that not more than 50 mL be given per site.\(^{[R-22]}\)

**Strengths usually available:**\(^{[R-21; 22]}\)

- **U.S.—**
  - Veterinary-labeled product(s):
    - 100 mg (base) per mL (Rx) [Adspec Sterile Solution].
  - Canada—
    - Veterinary-labeled product(s):
      - 100 mg (base) per mL (Rx) [Adspec Sterile Solution].

**Package and storage:** Store at 20 to 25 °C (68 to 77 °F), unless otherwise specified by the manufacturer.\(^{[R-22]}\) Protect from freezing.

**USP requirements:** Not in USP.\(^{[R-14]}\)

**References**


© 2008 The United States Pharmacopeial Convention

All rights reserved


23. Communication with Canadian gFARAD on May 24, 2008.