SPECTINOMYCIN Veterinary—Systemic

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

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

Category:

Antimicrobial (systemic).

Indications:

Note: Bracketed information in the *Indications* section refers to uses that either are not included in U.S. product labeling or are for products not commercially available in the U.S.

General considerations

Spectinomycin is an antibiotic that is active against a variety of aerobic gram-negative and gram-positive organisms **{R-3; 4}** as well as *Mycoplasma* species **{R-7}**. 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* **{R-25}**. Anaerobic organisms are generally resistant **{R-7}**. Spectinomycin is usually bacteriostatic at therapeutic doses **{R-5}**. 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 **{R-5}**.

Accepted

Air sacculitis (treatment)[1]—*Turkey poults,* 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 **{R-17}**.

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* **{R-2; 18}**.

Chronic respiratory disease (CRD) (treatment)—

Turkey poults, 1- to 3-day-old[1]: Spectinomycin hydrochloride injection is indicated to aid in the control of CRD associated with *Escherichia coli* **{R-17}**.

Chickens, broiler: Spectinomycin powder for oral solution is indicated to aid in the control of mortality due to CRD associated with susceptible *Mycoplasma gallisepticum* **{R-2; 18}**.

Colibacillosis (treatment)[1]—*Chicks,* newly hatched: Spectinomycin hydrochloride injection is indicated in the control of mortality and to lessen severity of infections caused by *E. coli* **{R-17}**.

Enteritis, bacterial (treatment)—*Piglets:* Spectinomycin oral solution is indicated in the treatment of bacterial enteritis (white scours) associated with *E. coli* in piglets younger than 4 weeks of age **{R-3; 4}**.

Paratyphoid (treatment)[1]—*Chicks,* newly hatched: Spectinomycin hydrochloride injection is indicated in the control of mortality and to lessen severity of infections caused by *Salmonella typhimurium* **{R-17}**.

Pneumonia, bacterial (treatment)—*Cattle:* Spectinomycin sulfate injection is indicated in the treatment of pneumonia (bovine respiratory disease) associated with *M. haemolytica, P. multocida,* and *H. somnus* in cattle **{R-21; 25}**.

Salmonella infantis infection (treatment)[1]—*Chicks,* newly hatched: Spectinomycin hydrochloride injection is indicated in the control of mortality and to lessen severity of infections caused by *S. infantis* **{R-**

17}; however, *S. infantis* is not considered to be a major pathogen in the poultry industry.

Synovitis (prophylaxis)—*Chickens*, broiler: Spectinomycin powder for oral solution is indicated to aid in the prevention of mortality associated with infectious synovitis due to susceptible *Mycoplasma synoviae* **{R-2; 18}**.

Synovitis (treatment)—

Chickens, broiler[1]: Spectinomycin powder for oral solution is indicated to aid in the control of mortality associated with infectious synovitis due to susceptible *M. synoviae* **{R-18}**.

Chicks, newly hatched[1]: Spectinomycin hydrochloride injection is indicated in the control of mortality and to lessen severity of infections caused by susceptible *M. synoviae* **{R-17}**.

[Fowl cholera (treatment)]—*Turkeys:* Spectinomycin hydrochloride injection is indicated to reduce mortality due to fowl cholera caused by sensitive strains of *Pasteurella multocida* **{R-1}**.

Acceptance not established

Colibacillosis (treatment)[1]—[*Ducklings*]: There are insufficient data to establish the safety and efficacy of spectinomycin in the treatment of colibacillosis in ducklings; however, in one study, subcutaneous administration of spectinomycin reduced the mortality and improved weight gain in 1-day-old ducklings experimentally infected with *E. coli* **{R-10}**.

Infections, bacterial (treatment), including

Respiratory tract infections (treatment)—[*Pigs*][1]: There are insufficient data to establish the safety and efficacy of spectinomycin injection in the treatment of respiratory infections and systemic infections due to susceptible organisms in pigs; however, the parenteral administration of spectinomycin to pigs has been used in clinical practice to treat these infections **{R-5}**.

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[1]Not included in Canadian product labeling or product not commercially available in Canada.

Regulatory Considerations

U.S.—

Spectinomycin oral solution is labeled for use in piglets younger than 4 weeks of age or weighing < 6.8 kg **{R-3; 4}**.

Spectinomycin injection is labeled for use only in newly hatched chicks and in 1- to 3-day-old turkey poults **{R-17}**.

Spectinomycin is not labeled for use in birds producing eggs for human consumption **{R-18}**.

Withdrawal times have been established for the use of spectinomycin in newly hatched chicks **{R-17}**, broiler chickens **{R-18}**, 1- to 3-day-old turkey poults **{R-17}**, and piglets **{R-4}** (see the *Dosage Forms* section).

Canada—

Spectinomycin is not labeled for use in birds producing eggs for human consumption **{R-1}**.

Spectinomycin injection is not labeled for use in turkeys weighing < 0.5 kg **{R-1}**.

Withdrawal times have been established for the use of spectinomycin in broiler chickens **{R-2}**, piglets **{R-3}**, and turkeys **{R-1}** (see the *Dosage Forms* section).

Chemistry

Source: Spectinomycin is a product of *Streptomyces spectabilis* **{R-5; 25}**.

Chemical group: Aminocyclitol **{R-5}**.

Chemical name:

Spectinomycin hydrochloride—4*H*-Pyrano[2,3-*b*][1,4]benzodioxin-4-one, decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-, dihydrochloride, pentahydrate **{R-6}**.

Spectinomycin sulfate tetrahydrate—Decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-b][1,4]benzodioxin-4-one sulfate, tetrahydrate **{R-25}**.

Molecular formula: Spectinomycin hydrochloride—$C_{14}H_{24}N_2O_7 \cdot 2HCl \cdot 5H_2O$ **{R-6}**.

Molecular weight: Spectinomycin hydrochloride—495.35 **{R-6}**.

Description: Spectinomycin Hydrochloride USP—White to pale-buff crystalline powder **{R-16}**.

pKa: 6.95 and 8.70 **{R-23}**.

Solubility: Spectinomycin Hydrochloride USP—Freely soluble in water; practically insoluble in alcohol, in chloroform, and in ether **{R-16}**.

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 **{R-7}**; some of the pharmacokinetic data in this section are derived from studies in which lincomycin and spectinomycin were administered concomitantly **{R-7}**.

Mechanism of action/Effect: Spectinomycin binds to the 30S ribosomal subunit of the microorganism and inhibits protein synthesis by preventing elongation of the polypeptide chain at the translocation step **{R-5}**.

Absorption: Spectinomycin is only slightly absorbed from the gastrointestinal tract **{R-7}**; however, it is rapidly absorbed following intramuscular administration **{R-7}**. In cattle, spectinomycin is completely bioavailable following intramuscular administration **{R-7}**. Repeated administration in cattle does not appear to result in tissue concentrations higher than those achieved with a single dose **{R-7}**.

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 **{R-7}**. An identical profile is seen in cattle 24 and 72 hours following intramuscular administration of spectinomycin **{R-7}**. Tissue/serum ratios of spectinomycin usually do not exceed 0.25 to 0.5 and are much lower in brain, aqueous humor, and bone **{R-22}**.

Volume of distribution (Vol_D):

Cows—0.295 Liter per kg (L/kg) **{R-13}**.

Ewes—0.307 L/kg **{R-13}**.

Protein binding: *Cows*—Low (approximately 10%) **{R-13}**.

Biotransformation: Spectinomycin does not appear to undergo any significant metabolism. In swine, it is excreted unchanged in the urine following intramuscular administration **{R-7}**.

Half-life: Elimination—

Cows: 1.01 **{R-13}** to 1.2 hours **{R-7}**.

Ewes: 1.01 hours **{R-13}**.

Pigs: 0.98 hour **{R-7}**.

Peak serum concentration/Time to peak serum concentration:

Calves, preruminating—20 mcg/mL between 0.33 and 0.67 hours following an intramuscular dose of 10 mg/mL **{R-7}**.

Cows—Approximately 55 micrograms per mL (mcg/mL) at 1 hour following an intramuscular dose of 20 mg per kg of body weight (mg/kg) **{R-13}**.

Dogs—

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

Oral **{R-7}**:

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

80 mcg/mL approximately 4 hours following a dose of 500 mg/kg.

Ewes—Approximately 53 mcg/mL at 1 hour following an intramuscular dose of 20 mg/kg **{R-13}**.

Elimination:

Following intramuscular administration—Spectinomycin is rapidly absorbed, then quickly eliminated from plasma and tissues through renal excretion **{R-7}**. Because of this rapid excretion, drug accumulation is not observed following repeated administration **{R-7}**. Renal impairment may cause accumulation of the active drug **{R-22}**.

Following oral administration—Because spectinomycin is poorly absorbed from the gastrointestinal tract, it is excreted mostly in the feces **{R-7}**.

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 **{R-13}**. 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 **{R-7}**. No residues of spectinomycin were detectable at the seventh milking **{R-7}**.

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

Incidence unknown

All species

***Anaphylactic reactions* {R-25}*; neuromuscular blockade* {R-5}**

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

Incidence unknown

Cattle

***Discoloration of tissue at the injection site;* {R-25} *swelling at the injection site, mild* {R-25}**

Human side/adverse effects {R-15}

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 **{R-25}**. Urinalysis was performed only on steers. Urinary pH was decreased and squamous and transitional cells were found in the urine **{R-25}**

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 **{R-1}*; coma*** **{R-1}**

Note: Clinical signs of *ataxia* and *coma* following a single, subcutaneous dose of 90 mg per poult were transient, resolving after 4 hours **{R-1}**; a single, subcutaneous injection of up to 50 mg per poult caused no detectable ill effects **{R-1}**.

Veterinary Dosing Information

Safety considerations

Some individuals who handle spectinomycin develop serious reactions involving skin, nails, and eyes **{R-1; 9}**. 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—*Piglets,* younger than 4 weeks of age:

For piglets 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 piglets 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}**.

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 (OT C) [*AmTech Spectam Scour-Halt; Spectam Scour-Halt*].

Canada—

For veterinary-labeled product(s):

50 mg (base) per mL (OTC) [*Spectam Oral Solution; Spectam Scour-Halt*].

Withdrawal times:

U.S. and Canada **{R-3; 4; 19}**—

	Withdrawal time
Species	Meat (days)
Pigs	21

Note: The above withdrawal time applies when medication is administered at a total dose of 50 mg (base) two times a day for piglets weighing less than 4.5 kg or 100 mg (base) two times a day for piglets weighing 4.5 kg to 6.8 kg, for a maximum duration of five days **{R-3; 4}**.

Packaging and storage: Store below 23 °C (73 °F). Do not freeze **{R-3; 4}**.

Auxiliary labeling: When not in use, the plastic doser should be removed and the original cap replaced on bottle **{R-3; 4}**. The plastic doser should be rinsed with water after each use.

USP requirements: Not in USP **{R-16}**.

SPECTINOMYCIN HYDROCHLORIDE POWDER FOR ORAL SOLUTION

Usual dose:

Chronic respiratory disease (prophylaxis and treatment)—*Chickens,* broiler: Oral, administered as the sole source of drinking water at a concentration of 0.5 mg (base) per mL (2 grams [base] per

gallon) of water for the first three days of life and for one day following each vaccination **{R-2; 18; 24}**.

Synovitis (prophylaxis and treatment[1])—*Chickens*, broiler: Oral, administered as the sole source of drinking water at a concentration of 0.26 mg (base) per mL (1 gram [base] per gallon) of water for the first three to five days of life **{R-18; 24}**.

Note: Canadian labeling lists a dose of 0.5 mg (base) per mL (2 grams [base] per gallon) of water for this indication **{R-2}**.

Strength(s) usually available:

U.S.—

Veterinary-labeled product(s):

500 mg (base) per gram of water-soluble powder (OTC) [*Spectam Water Soluble*].

Canada—

Veterinary-labeled product(s):

500 mg (base) per gram of water-soluble powder (OTC) [*Spectam Soluble Powder*].

Withdrawal times:

U.S. and Canada **{R-2; 18; 24}**—

Species	Withdrawal time Meat (days)
Chickens	5

Note: The above withdrawal time applies when medication is administered in the drinking water up to a maximum concentration of 0.5 mg (base) per mL for up to a maximum duration of 5 days **{R-2; 18}**.

Products are not labeled for use in poultry laying eggs for human consumption **{R-24}**.

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: Bracketed information in the *Dosage Forms* section refers to uses that either are not included in U.S. product labeling or are for products not commercially available in the U.S.

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)[1]—*Turkey poults*, 1- to 3-day-old: Subcutaneous in cervical area, 10 mg (base) as a single, total dose per poult **{R-17}**.

Chronic respiratory disease (treatment)[1]—*Turkey poults*, 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}**.

Colibacillosis (treatment)[1];

Paratyphoid (treatment)[1];

Salmonella infantis infection (treatment)[1]; or

Synovitis (treatment)[1]—*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}**.

[Fowl cholera (treatment)]—*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 observed **{R-1}**. Treatment must not be

repeated within five days of the initial treatment **{R-1}**.

Note: [*Ducklings*][1]—For use in animals not to be used in food production: Although there are insufficient data to establish safety and efficacy, a single, subcutaneous, total dose of 5 mg (base) per duckling has been shown to reduce mortality and improve weight gain in one-day-old ducklings experimentally infected with *E. coli* **{R-10}**.

[*Pigs*][1]—Although there are insufficient data to establish safety and efficacy, the intramuscular administration of spectinomycin to pigs, at doses ranging from 6.6 to 22 mg (base) per kg of body weight every twelve to twenty-four hours **{R-11}**, has been used in clinical practice to treat *respiratory infections* and *systemic infections* caused by organisms sensitive to spectinomycin **{R-5}**.

Strength(s) usually available {R-22}:

U.S.—

Veterinary-labeled product(s):

100 mg (base) per mL (OTC) [GENERIC] **{R-17}**.

Canada—

Veterinary-labeled product(s):

100 mg (base) per mL (OTC) [*Spectam; Spectam Injectable*] **{R-1}**.

Withdrawal times:

Note: *Pigs*—Because injectable spectinomycin is not labeled for use in pigs, there are no established withdrawal times in the U.S. or Canada. If spectinomycin is administered intramuscularly at a dose of 20 mg per kg of body weight, evidence has been compiled by the Food Animal Residue Avoidance Databank (FARAD) that suggests a meat withdrawal time of thirty days would be sufficient to avoid violative residues **{R-7; 14}**.

U.S. **{R-17}**—

	Withdrawal time
Species	Meat (days)
Chicks, newly hatched	0
Turkey poults, 1- to 3-day-old	0

Note: The above withdrawal time applies when medication is administered up to a maximum dose of 5 mg per animal in chicks and 10 mg per animal in turkey poults as a single injection **{R-17}**.

Canada **{R-2}**—

	Withdrawal time
Species	Meat (days)
Turkeys	5

Note: The above withdrawal time applies when medication is administered up to a maximum dose of 22 mg per kg of body weight as a single injection. **{R-1}**

Preparation of dosage form:

Dilution with sterile physiologic saline according to product labeling is recommended when administering total doses < 5 mg and is appropriate when large flocks are being treated **{R-17}**. Aseptic technique must be employed and unused diluted solution should be discarded **{R-17}**.

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from freezing **{R-17}**.

Auxiliary labeling: Injection site should be disinfected prior to injection and precautions should be taken to prevent contamination of the contents of the bottle **{R-1; 17}**.

USP requirements: Not in USP **{R-16}**.

SPECTINOMYCIN SULFATE INJECTION

Usual dose: Pneumonia—*Cattle:* Subcutaneous, 10 to 15 mg (base) per kg of body weight every twenty-four hours for three to five days **{R-25}**.

Note: It is recommended that this medication be administered subcutaneously in the neck and that not more than 50 mL be given per site **{R-25}**.

Strength(s) usually available {R-21; 22; 25}:

U.S.—

Veterinary-labeled product(s):

100 mg (base) per mL (Rx) [*Adspec Sterile Solution; Bovispec Sterile Solution*].

Canada—

Veterinary-labeled product(s):

100 mg (base) per mL (Rx) [*Adspec Sterile Solution*].

Withdrawal times:

U.S.—

Species	Withdrawal time Meat (days)
Cattle	11

Note: Product labeling listing the above withdrawal time states that withdrawal times have not been established for preruminating calves or for lactating dairy cattle and that it should not be used in female dairy cattle 20 months of age or older or in calves to be procesed for veal **{R-25}**. Discoloration of tissue at the injection site may last more than 11 days, making it necessary to trim the site and surrounding tissue at slaughter **{R-25}**.

Canada **{R-21}**—

Species	Withdrawal time Meat (days)
Cattle	11

Note: Product labeling listing the above withdrawal time states that it applies to a dosage of 10 mg per kg of body weight every twenty-four hours for three to five days.

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

USP requirements: Not in USP **{R-16}**.

[1]Not included in Canadian product labeling or product not commercially available in Canada.

Developed: 07/08/98
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