

Dosage Forms/Approval

VETERINARY-LABELED PRODUCTS: None

The ARCI (Racing Commissioners International) has designated this drug as a class 3 substance. See the appendix for more information.

HUMAN-LABELED PRODUCTS:

Sotalol HCl Tablets: 80 mg, 120 mg, 160 mg & 240 mg; *Betapace*® & *Betapace*® AF (Berlex); generic; (Rx)

SPECTINOMYCIN HCL SPECTINOMYCIN SULFATE

(spek-ti-noe-mye-sin) Adspec®, Spectam®

AMINOCYCLITOL ANTIBIOTIC

Prescriber Highlights

- ▶ Aminocyclitol antibiotic used primarily in food producing animals; relatively broad spectrum but minimal activity against anaerobes & most strains of *Pseudomonas*
- ▶ Contraindications: Hypersensitive to it
- ▶ Adverse Effects: Appears to have minimal adverse effects at labeled dosages; probably less nephrotoxicity/ototoxicity than other aminocyclitols. Can cause neuromuscular blockade. May cause swelling at SC injection sites.

Uses/Indications

Although occasionally used in dogs, cats, and horses for susceptible infections, Spectinomycin only has approved dosage forms for cattle, chickens, turkeys, and swine. Refer to the Dosage section below for more information on approved uses.

Pharmacology/Actions

Spectinomycin is primarily a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria by binding to the 30S ribosomal subunit.

Spectinomycin has activity against a wide variety of gram-positive and gram-negative bacteria, including *E. coli*, *Klebsiella*, *Proteus*, *Enterobacter*, *Salmonella*, *Streptococci*, *Staphylococcus*, and *Mycoplasma*. It has minimal activity against anaerobes, most strains of *Pseudomonas*, *Chlamydia*, or *Treponema*.

In human medicine, spectinomycin is used principally for its activity against *Neisseria gonorrhoeae*.

Pharmacokinetics

After oral administration only about 7% of the dose is absorbed, but the drug that remains in the GI tract is active. When injected SC or IM, the drug is reportedly absorbed well with peak levels occurring in about 1 hour.

Tissue levels of absorbed drug are lower than those found in the serum. Spectinomycin does not appreciably enter the CSF or the eye and is not bound significantly to plasma proteins. It is unknown whether spectinomycin crosses the placenta or enters milk.

Absorbed drug is excreted via glomerular filtration into the urine mostly unchanged. In cattle, terminal half-life is about 2 hours.

Contraindications/Precautions/Warnings

Spectinomycin is contraindicated in patients hypersensitive to it.

Adverse Effects

When used as labeled, adverse effects are unlikely with this drug. It is reported that parenteral use of this drug is much safer than with other aminocyclitol antibiotics, but little is known regarding its prolonged use. It is probably safe to say that spectinomycin is significantly less ototoxic and nephrotoxic than other commonly used aminocyclitol antibiotics, but can cause neuromuscular blockade. Parenteral calcium administration will generally reverse the blockade.

Adverse effects that have been reported in human patients receiving the drug in single or multidose studies include soreness at injection site, increases in BUN, alkaline phosphatase and SGPT, and decreases in hemoglobin, hematocrit, and creatinine clearance. Although increases in BUN and decreases in creatinine clearance and urine output have been noted, overt renal toxicity has not been demonstrated with this drug.

Cattle receiving the sulfate form subcutaneously have developed swelling at the injection site.

Reproductive/Nursing Safety

In humans, the FDA categorizes this drug as category *B* for use during pregnancy (*Animal studies have not yet demonstrated risk to the fetus, but there are no adequate studies in pregnant women; or animal studies have shown an adverse effect, but adequate studies in pregnant women have not demonstrated a risk to the fetus in the first trimester of pregnancy, and there is no evidence of risk in later trimesters.*)

It is not known whether spectinomycin is excreted in milk; use caution when administering to nursing patients.

Overdosage/Acute Toxicity

No specific information was located on oral overdoses, but because the drug is negligibly absorbed after oral administration, significant toxicity is unlikely via this route.

Injected doses of 90 mg produced transient ataxia in turkey poults.

Drug Interactions

- Antagonism has been reported when spectinomycin is used with **chloramphenicol** or **tetracycline**.

Doses

■ DOGS:

For susceptible infections:

- a) 5.5–11 mg/kg q12h IM or 22 mg/kg PO q12h (for enteric infections; not absorbed) (Kirk 1989)
- b) 5–10 mg/kg IM q12h (Davis 1985)
- c) For acute infectious gastroenteritis: 5–12 mg/kg IM q12h (DeNovo 1986)

■ CATS:

For susceptible infections:

- a) For acute infectious gastroenteritis: 5–12 mg/kg IM q12h (DeNovo 1986)

■ CATTLE:

For susceptible infections:

- a) For bronchopneumonia and fibrinous pneumonia: 33 mg/kg SC q8h. Suggested withdrawal time is 60 days. (Hjerpe 1986)
- b) 22–39.6 mg/kg/day IM divided three times daily (Upson 1988)
- c) For bovine respiratory disease: 10–15 mg/kg SC (in the neck; not more than 50 mL per site) once daily (q24h) for 3–5 consecutive days (Label directions; *Adspec*®)

■ HORSES:

For susceptible infections:

- 20 mg/kg, IM three times daily (Robinson 1987)
- For pneumonia: 20 mg/kg IM q8h; may cause local myositis. Insufficient data to comment on use. (Beech 1987b)

■ SWINE:

For susceptible enteric infections:

- 10 mg/kg, PO q12h (Howard 1986)
- For bacterial enteritis (white scours) in baby pigs associated with *E. coli* susceptible to spectinomycin: 50 mg/10 lbs of body weight PO twice daily for 3–5 days (Label directions; *Spectam Scour-Halt*®—Ceva)
- 10 mg/kg, IM q12h (Baggot 1983)

■ BIRDS:

- For airsacculitis associated with *M. meleagridis* or chronic respiratory disease associated with *E. coli* in turkey poults (1–3 days old): Inject 0.1 mL (10 mg) SC in the base of the neck.

For control and to lessen mortality due to infections from *M. synoviae*, *S. typhimurium*, *S. infantis*, and *E. coli* in newly hatched chicks: Dilute injection with normal saline to a concentration of 2.5–5 mg/0.2 mL and inject SC. (Label directions; *Spectam*® *Injectable*—Ceva)

- For prevention and control of chronic respiratory disease associated with *Mycoplasma gallisepticum* in broilers: Add sufficient amount to drinking water to attain a final concentration of 2 g/gallon.

For infectious synovitis associated with *Mycoplasma synoviae* in broilers: Add sufficient amount to drinking water to attain a final concentration of 1 g/gallon.

For improved weight gain/feed efficiency in floor-raised broilers: Add sufficient amount to drinking water to attain a final concentration of 0.5 g/gallon. (Label directions; *Spectam*® *Water-Soluble*—Ceva)

Monitoring

- Clinical efficacy

Chemistry/Synonyms

An aminocyclitol antibiotic obtained from *Streptomyces spectabilis*, spectinomycin is available as the dihydrochloride pentahydrate and hexahydrate sulfate salts. It occurs as a white to pale buff, crystalline powder with pK_{as} of 7 and 8.7. It is freely soluble in water and practically insoluble in alcohol.

Spectinomycin may also be known as: M-141, actinospectacin, spectinomycini, U-18409AE, *Adspec*®, *Amtech Spectam*®, *Kempi*®, *Kirin*®, *Spectoguard Scour-Chek*®, *Stanilo*®, *Togamycin*®, *Trobicin*®, *Trobicine*®, or *Vabicin*®.

Storage/Stability

Unless otherwise instructed by the manufacturer, spectinomycin products should be stored at room temperature (15–30°C). Protect from freezing.

Dosage Forms/Regulatory Status**VETERINARY-LABELED PRODUCTS:**

Spectinomycin Sulfate Injection: 100 mg/mL in 500 mL vials; *Adspec*®; (Pharmacia & Upjohn); (Rx). When used as labeled, slaughter withdrawal in cattle = 11 days; not to be used in veal calves or in dairy cattle 20 months of age or older.

Spectinomycin Injection: 100 mg/mL in 500 mL vials; *Amtech Spectam*® *Injectable* (IVX); (OTC). Approved for use in 1–3 days old turkey poults and newly hatched chicks.

Spectinomycin Water Soluble Concentrate: 0.5 g of spectinomycin per gram *Spectam*® *Water Soluble* (Bimeda); (OTC). Approved for use in chickens (not layers). Slaughter withdrawal (at labeled doses) = 5 days.

Spectinomycin Oral Solution: 50 mg/mL in 240 mL pump bottle and 500 and 1000 mL without pump; *Amtech Spectam Scour-Halt*®, (IVX), *Spectoguard Scour-Chek*® (Bimeda), *Spectam Scour-Halt*®, (AgriPharm); (OTC). Approved for use in swine (Weighing less than 15 lbs and not older than 4 weeks of age). Slaughter withdrawal (at labeled doses) = 21 days.

Spectinomycin/Lincomycin in a 2:1 ratio

LS 50 Water Soluble Powder® (Pharmacia & Upjohn); *Sepclinx-50*® (Bimeda); generic (IVX, AgriLabs); in 2.65 oz packets. Each packet contains lincomycin 16.7 g and spectinomycin 33.3 g. Approved for use in chickens up to 7 days of age.

Lincomycin 50 mg/Spectinomycin 100 mg per mL in 20 mL vials; *Linco-Spectin*® *Sterile Solution* (Pharmacia & Upjohn); (OTC). Approved for use in semen extenders only.

HUMAN-LABELED PRODUCTS:

Spectinomycin Powder for Injection: 400 mg (as the HCl) per mL after reconstitution in 2 g vial with 3.2 mL diluent; *Trobicin*® (Upjohn); (Rx)

SPIRONOLACTONE

(speer-on-oh-lak-tone) Aldactone®

ALDOSTERONE ANTAGONIST**Prescriber Highlights**

- Aldosterone antagonist used as a potassium sparing diuretic or for adjunctive treatment for heart failure (use is somewhat controversial for CHF in dogs); should not be substituted for furosemide in CHF
- Contraindications: Hyperkalemia, Addison's disease, anuria, acute renal failure or significant renal impairment
- Caution: Any renal impairment or hepatic disease
- Adverse Effects: Hyperkalemia, hyponatremia, & dehydration; increased BUN & mild acidosis in patients with renal impairment. GI distress (vomiting, anorexia, etc.), CNS effects (lethargy, ataxia, headache, etc.), & endocrine changes possible

Uses/Indications

Spironolactone may be used in patients with congestive heart failure who do not adequately respond to furosemide and ACE inhibitors, who develop hypokalemia on other diuretics, and are unwilling or unable to supplement with exogenous potassium sources. It may also be effective in treating ascites as it has less potential to increase ammonia levels than other diuretics.

Pharmacology/Actions

Aldosterone is competitively inhibited by spironolactone in the distal renal tubules with resultant increased excretion of sodium, chloride, and water, and decreased excretion of potassium, ammonium, phosphate, and titratable acid. Spironolactone has no effect on carbonic anhydrase or renal transport mechanisms and has its greatest effect in patients with hyperaldosteronism. When used alone in