

VÉTOQUINOL USA, INC.

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SUROLAN® OTIC SUSPENSION



Vétoquinol USA

miconazole nitrate, polymyxin B sulfate, prednisolone acetate

For otic use In dogs only

CAUTION

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

SUROLAN Otic Suspension contains 23 mg/mL miconazole nitrate, 0.5293 mg/mL polymyxin B sulfate and 5 mg/mL prednisolone acetate. Inactive ingredients are colloidal silicon dioxide and liquid paraffin.

INDICATIONS FOR USE

SUROLAN is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to polymyxin B and miconazole.

DOSAGE AND ADMINISTRATION

The external ear should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. Instill 5 drops of SUROLAN twice daily into the ear canal and massage the ear. Therapy should continue for 7 consecutive days. Shake well before use.

CONTRA-INDICATIONS

Concomitant use of drugs known to induce ototoxicity should be avoided. Do not use in dogs with known perforated tympanum.

PRECAUTIONS

Not for use in humans. Keep this and all drugs out of reach of children.

Before instilling any medication into the ear, examine the external ear canal thoroughly to be certain the tympanic membrane is not ruptured in order to avoid the possibility of transmitting infection to the middle ear as well as damaging the cochlea or vestibular apparatus from prolonged contact. Long-term administration of topical corticosteroid products may result in delayed wound healing. If overgrowth of non-susceptible bacteria or fungi occurs, treatment should be discontinued and appropriate therapy instituted.

For topical use only. Avoid ingestion. Adverse systemic reactions have been observed following accidental oral ingestion of some topical corticosteroid preparations. Patients should be closely observed for the usual signs of adrenocorticoid overdosage which includes sodium retention, potassium loss, fluid retention, weight gain, polydipsia, and/or polyuria. Prolonged use or overdosage may produce adverse immunosuppressive effects. Use of corticosteroids, depending on dose, duration, and specific steroid, may result in endogenous steroid production inhibition following drug withdrawal. In patients presently receiving or recently withdrawn from corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in especially stressful situations.

Adverse Reactions

In a field study with SUROLAN, few adverse events were reported. Most of them were considered as not related to SUROLAN treatment. Two dogs experienced reduced hearing while on treatment, on follow-up one dog reversed its hearing capacity to normal. No information could be collected from the other case since it was not available for follow-up.

Reported foreign market adverse reactions include topical hypersensitivity and reduced hearing or deafness.

CLINICAL PHARMACOLOGY

Miconazole nitrate: miconazole is a synthetic imidazole derivative with a high antifungal activity and a strong antibacterial activity against Gram-positive bacteria including *Staphylococcus aureus* and *Staphylococcus pseudintermedius* (formerly referred to as *S. intermedius*²).

Miconazole nitrate has been demonstrated to be effective *in vivo* and *in vitro* in the treatment of canine and feline dermatomycosis caused by *Microsporum canis* and/or *Trichophyton mentagrophytes*. *In vitro* efficacy against a number of pathogenic fungi including *Microsporum gypseum* and *Trichophyton interdigitale* is also attributed to miconazole nitrate. Miconazole nitrate has demonstrated *in vitro* and *in vivo* efficacy in dogs against several species of yeast including *Malassezia pachydermatis* isolated from cases of canine *otitis externa*.

Polymyxin B sulfate: polymyxin B is a broad-spectrum polypeptide antibiotic. The bactericidal properties of polymyxin B sulfate against Gram-negative bacteria, such as *Escherichia coli* and *Pseudomonas aeruginosa*, are well established. Moreover, a dual and even synergistic interaction has been shown to exist between miconazole nitrate and polymyxin B sulfate against *E. coli* and *S. aureus*.

Prednisolone acetate: prednisolone is a glucocorticoid with a strong anti-inflammatory activity and minimal effects on carbohydrate and mineral metabolism.

The anti-inflammatory and antipruritic properties of prednisolone are well known.

Miconazole nitrate-polymyxin B sulfate-prednisolone acetate: by virtue of its 3 active ingredients, SUROLAN has antibacterial, antifungal and anti-inflammatory activity. In component efficacy studies, the compatibility and additive effect of each of the components were demonstrated.

An *in vitro* study determined that polymyxin B sulfate and miconazole nitrate inhibit the growth of bacteria and yeast commonly associated with canine *otitis externa* (*S. pseudintermedius*², *P. aeruginosa*, *E. coli* and *M. pachydermatis*). Furthermore, a synergistic effect of the two antimicrobials was demonstrated against *P. aeruginosa* and *E. coli*. The addition of prednisolone acetate to the combination did not impair antimicrobial activity to any clinically-significant extent.

A study performed using an experimentally-induced model of ear inflammation in mice demonstrated the efficacy of prednisolone acetate in treating ear inflammation either alone or in combination with the other active ingredients of SUROLAN.

Effectiveness

In a clinical field trial in the US and Canada, including 337 dogs, SUROLAN was highly effective in the treatment of *otitis externa* associated with bacteria and *M. pachydermatis*. SUROLAN reduced pain, redness, swelling and exudate. SUROLAN has also been demonstrated to be active against ear mites (*Otodectes cynotis*)¹.

Animal Safety

The following adverse reactions were reported in a study when SUROLAN was administered at 1X, 3X and 5X for 42 consecutive days (6 times the recommended treatment duration) in laboratory Beagles: hypersensitivity reactions which included mild erythema and hyperemia, painful and sensitive ear canals on examination, changes in hematology, clinical chemistry and urinalysis values consistent with the systemic absorption of topical corticosteroids, and veterinary observations of pale ear canals.

HOW SUPPLIED/STORAGE and HANDLING

SUROLAN is available in 15 mL and 30 mL plastic dispensing bottles with applicator tip for otic use.

Store at or below 25 °C (77 °F).

For technical assistance or to report adverse reactions call 1-800-835-9496.

NADA 141-298, Approved by FDA.

NADA holder: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

Made in Belgium for Vétquinol USA Inc., Ft. Worth TX (USA) 76137

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REFERENCES

1. Engelen M. and Anthonissens E. (2000).

Efficacy of non-acaricidal-containing otic preparations in the treatment of otoacariasis in dogs and cats. The Veterinary Record 147(20):567-569.

2. Devriese L.A., Hermans K., Baele M. and Haesebrouck F. (2009).

Staphylococcus pseudintermedius versus *Staphylococcus intermedius*.

Veterinary Microbiology 133(1-2):206-207.

US - AW_44448

	NDC	
15 ML	17030-947-15	0609 D, 0609 B
30 ML	17030-947-30	0609 D, 0609 C

NAC No.: 10050920

Tetracycline is a bacteriostatic antibiotic used by veterinarians for the treatment of infections such as Lyme disease, Chlamydia, Rocky Mountain Spotted Fever and bacterial infections caused by susceptible organisms.

Availability

Tetracycline is a prescription medication available as capsules and syrup.

How this medicine should be used

Tetracycline is FDA approved for use in dogs and cats. The usual dose of tetracycline in dogs is 10mg/pound every 8 hours. The usual dose of tetracycline in cats is 9mg/pound every 8-12 hours.

Side effects

Side effects of tetracycline include vomiting, diarrhea, loss of appetite and drowsiness.

Special precautions

Tetracycline should not be used in animals allergic to it or other drugs in this class. Use with caution in animals with impaired liver or kidney function. Do not use in pregnant, nursing, or growing animals since this medication may cause slowing of bone growth and discoloration of teeth. Give antacids, vitamin and mineral combinations, iron, or Pepto-Bismol at least 1 hour before or 4 hours after giving tetracycline. Use caution when given with digoxin or warfarin. Tetracycline should be given on an empty stomach.

In the event of an overdose

Contact your veterinarian or veterinary emergency room. Symptoms of overdose may include diarrhea, vomiting and lack of appetite.

Storage

Keep this medication in the container it came in, tightly closed. Store at room temperature, away from excess heat, light and moisture. Do not store in the bathroom. Throw away any medication that is outdated or no longer needed. Keep out of the reach of children and pets.