

A Strong, Yet Gentle Solution for
Severe Cases of Otitis Externa

POSATEX[®]

Otic Suspension

A TRIPLE ACTION, ONCE-A-DAY
SOLUTION FOR ALL THREE
PRIMARY PATHOGENS.¹



 **Posatex[®]**
Otic Suspension
(Orbifloxacin, Mometasone
Furoate Monohydrate and
Posaconazole, Suspension)

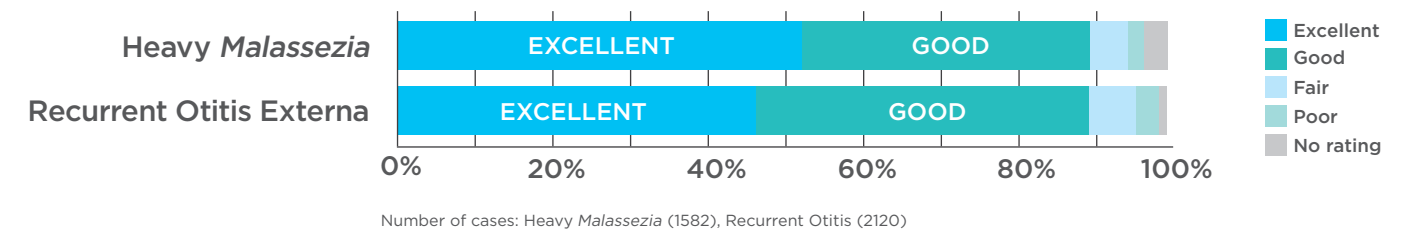
POSATEX® VETERINARY CLINICAL IMPRESSION STUDY

TREAT OTITIS EXTERNA THE FIRST TIME

Clinic survey results from 3,923 patient assessments showed Posatex® gets strong performance scores from veterinarians, even on the toughest, most chronic cases of otitis externa.

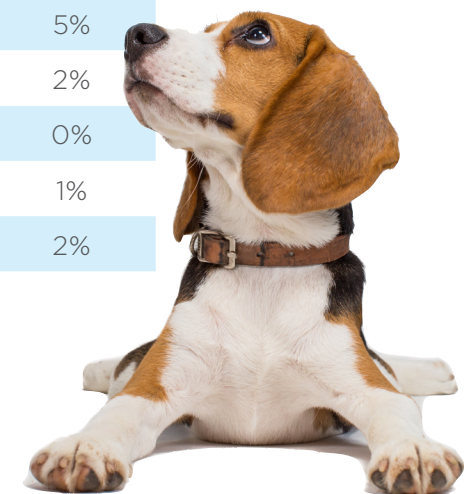


Veterinarians use Posatex® most often to treat recurrent otitis externa and cases with heavy *Malassezia* infection, and they report **excellent treatment results with Posatex®.**¹



POSATEX® PERFORMANCE IS CONSISTENT REGARDLESS OF PRIMARY FACTORS.¹

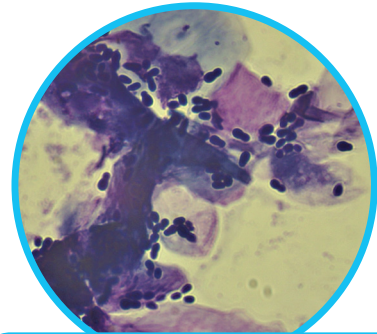
| | Excellent | Good | Fair | Poor | No Answer |
|-----------------------------|-----------|------|------|------|-----------|
| Atopy (1673) | 49% | 39% | 6% | 2% | 3% |
| Seborrhea (328) | 45% | 44% | 6% | 2% | 3% |
| Parasites (37) | 46% | 41% | 8% | 0% | 5% |
| Food Allergy (578) | 45% | 44% | 6% | 2% | 2% |
| Foreign Body (27) | 44% | 48% | 4% | 4% | 0% |
| Hypothyroidism (129) | 43% | 50% | 2% | 5% | 1% |
| Other (522) | 48% | 41% | 7% | 2% | 2% |



TRIPLE-ACTION ONCE-A-DAY POSATEX®

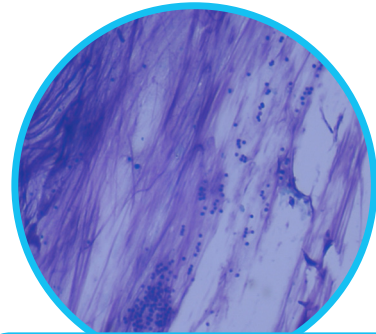
DELIVERS FAST, EFFECTIVE TREATMENT FOR SEVERE AND CHRONIC CASES OF OTITIS EXTERNA

Photos used with permission from Animal Dermatology South, LLC



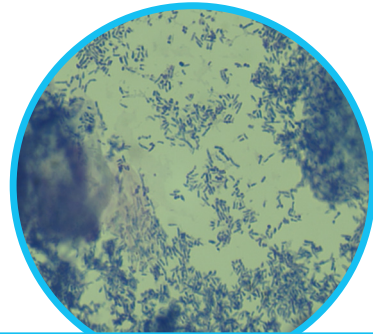
YEAST

Malassezia pachydermatis



COCCOID BACTERIA

Coccoid bacteria with nuclear streaming



ROD BACTERIA

OTITIS EXTERNA: A COMPLEX AND PERPETUATING CONDITION

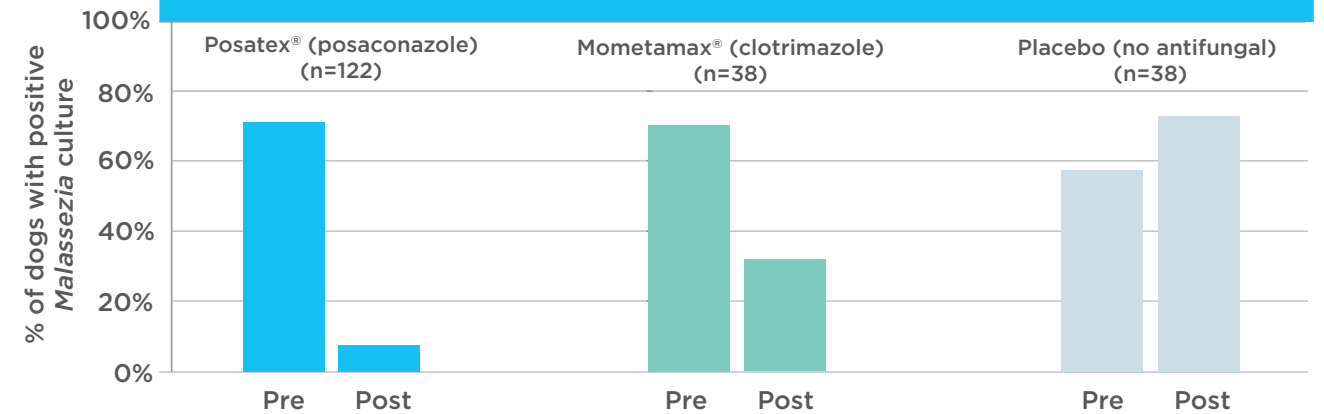
Otitis externa can be triggered by allergy, injury, ectoparasites, or other causes of inflammation. Chronic or recurrent infection can cause damage to the ear canals. Posatex® offers a potent once-a-day combination that takes treatment to the next level.



POSACONAZOLE NOVEL TRIAZOLE ANTIFUNGAL

Posaconazole is particularly effective against *Malassezia pachydermatis*, an advantage when treating acute and recurrent *Malassezia* infections, and in cases of hypersensitivity to *Malassezia*.

Potent Antifungal Activity Demonstrated in Multi-Clinic Field Trial: Effect of treatment on presence of *Malassezia* spp. on fungal culture



Randomized, blinded, multi-clinic field trial in client-owned dogs with otitis externa. Dogs were treated once daily for 7 days. Dogs were evaluated pre-treatment and post-treatment. Final evaluation was conducted at least 48 hours after the last dosing.

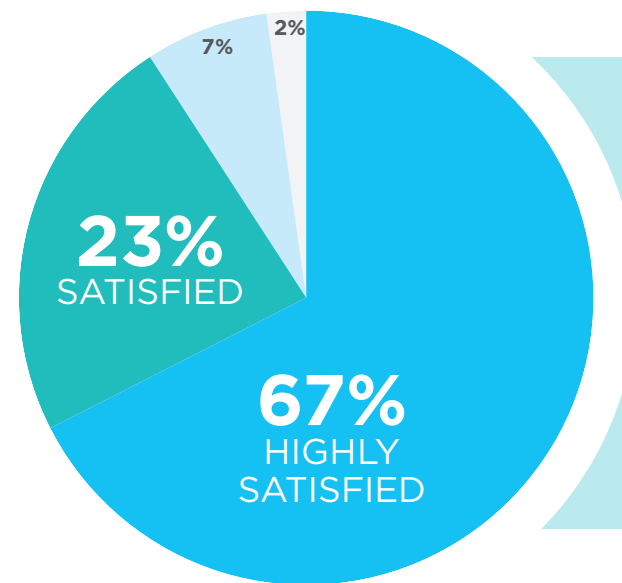
Under clinical field conditions, Posatex®, containing 0.1% posaconazole, eliminated *Malassezia* spp. in nearly all infected ears of dogs.¹

In vitro posaconazole proved to be at least 10 times more potent than other veterinary antifungals.¹

Veterinarians saw excellent or good resolution of heavy *Malassezia* with Posatex® in 89% of all cases¹

DOG OWNER SURVEY¹

REMARKABLE SATISFACTION RATES FROM POSATEX[®]



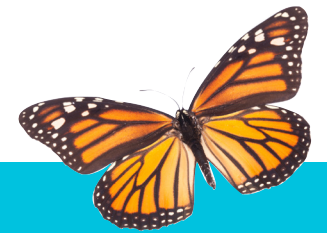
90% Satisfaction with Posatex[®]

67% of dog owners were highly satisfied with Posatex[®], and 23% said they were satisfied

- Highly Satisfied
- Satisfied
- Somewhat Satisfied
- Not Satisfied

Number of dog owners: 414

LISTEN TO WHAT DOG OWNERS HAVE TO SAY ABOUT POSATEX[®]



I could not believe this medicine worked so quickly. After months and months of ear odor and discharge, it seemed to clear this up in one day. I'm so grateful that my vet recommended this for my dog.

- Karen Mucci, Columbia, South Carolina

After a year of treating chronic yeast infections with other medications, Posatex[®] was the only medicine that has cleared the infection! As a long time hound owner, I am accustomed to my dogs having multiple infections and am very pleased with the treatment.

- Kristin Whipkey, North Tonawanda, New York

Our dog had been using a different eardrop for several months, noticed almost immediate improvement when changed to Posatex[®] drops. Our dog is finally free of ear infection!!!

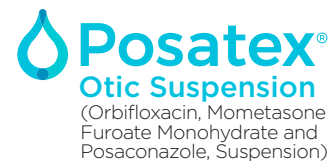
- Kathy Root, Liverpool, New York

POSATEX[®] PROVIDES RAPID RELIEF TO PETS

80% OF DOG OWNERS SAW AN IMPROVEMENT IN THEIR PET WITHIN 3 DAYS OF TREATMENT

| | 1 day | 1.5 days | 2 days | 3 days |
|------------------------------------|------------|------------|------------|------------|
| Head Shaking | 27% | 38% | 26% | 26% |
| Scratching | 28% | 36% | 20% | 27% |
| Odor | 23% | 38% | 22% | 26% |
| Head Rubbing | 20% | 23% | 19% | 22% |
| Redness | 27% | 38% | 23% | 26% |
| Discharge | 23% | 23% | 18% | 24% |
| Other | 4% | 4% | 7% | 4% |
| Total % who saw improvement | 19% | 32% | 58% | 80% |

Number of dog owners: 418



LISTEN TO WHAT **VETERINARIANS** HAVE TO SAY ABOUT POSATEX[®]



This dog had the worst otitis externa I had seen. The canals were inflamed. After 2 weeks still only slightly improved with a different medication, but after 1 week of Posatex[®] ears were dramatically better – back to normal. Owners are thrilled.

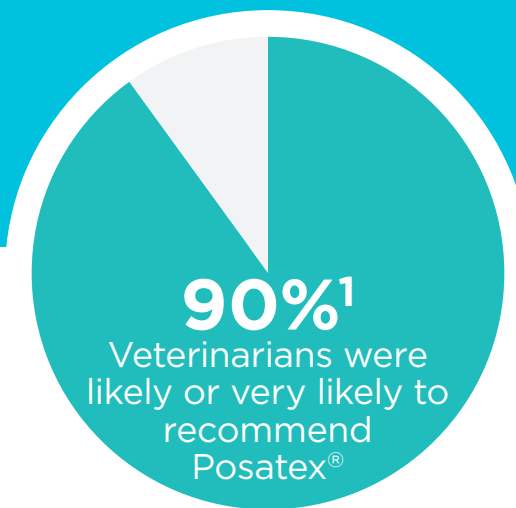
- Holly Brown, Northern Rhode Island Animal Hospital, Forestdale, Rhode Island

Once-daily administration very convenient, product well tolerated by patient, excellent clinical results in this patient.

- Dr. Walter Grambow, Plaistow Animal Medical Center, Kingston, New Hampshire

I am very impressed with the efficiency of this product in this patient who has struggled with chronic otitis for years!

- John DeVries, Oradell Veterinary Group, Hasbrouck Heights, New Jersey



Posatex[®]
Otic Suspension
(Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension)

MERCK ANIMAL HEALTH, THE LEADER IN OTIC CARE¹

IS COMMITTED TO RESEARCH AND DEVELOPMENT OF NOVEL TREATMENTS FOR EFFECTIVE RESOLUTION OF OTITIS EXTERNA.

ORBIFLOXACIN BROAD-SPECTRUM ANTIBIOTIC

Proven efficacy against Gram+ and Gram- bacteria associated with canine otitis externa, including *Staphylococcus* spp., the most common bacterial isolate, and *Pseudomonas aeruginosa*, associated with severe chronic inflammation and ulceration.

MOMETASONE FUROATE MONOHYDRATE POTENT ANTI-INFLAMMATORY

1% mometasone furoate monohydrate in Posatex[®] provides proven anti-inflammatory effect:^{1,2}

- more potent than betamethasone valerate
- rapidly reduces pain, erythema, and swelling
- prevents self-mutilation

No adrenocortical suppression at 3 times recommended dose for 21 days.^{1,2}

GOOD MARGIN OF ADRENAL SAFETY^{1,2}

Cortisol levels before and 1 hour after ACTH stimulation:

- Normal range in dogs treated at 3x recommended dose of Posatex[®] for 21 days
- Only slight decrease in cortisol levels in dogs treated with 5x recommended dose—after 21 days of treatment
- At 21 days the adrenal glands responded well to ACTH stimulation

No evidence of Cushing's syndrome

No changes in adrenal weights or microscopic appearance



Posatex™ Otic Suspension

(Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension)

Antibacterial, anti-inflammatory, antifungal

For Otic Use in Dogs Only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Federal law prohibits the extralabel use of this drug in food-producing animals.

DESCRIPTION: Each gram of POSATEX™ Otic Suspension contains 10 mg of orbifloxacin; mometasone furoate monohydrate equivalent to 1 mg mometasone furoate; and 1 mg of posaconazole in a mineral oil based system containing a plasticized hydrocarbon gel.

Four drops of POSATEX™ Otic Suspension delivers approximately 1.0 mg orbifloxacin, 0.1 mg of mometasone furoate monohydrate, and 0.1 mg of posaconazole.

INDICATIONS: POSATEX™ Otic Suspension is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*).

DOSAGE AND ADMINISTRATION: Shake well before use. For dogs weighing less than 30 lbs. instill 4 drops of POSATEX™ Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs. or more, instill 8 drops once daily into the ear canal. Therapy should continue for 7 consecutive days.

CONTRAINDICATIONS: POSATEX™ Otic Suspension is contraindicated in dogs with known or suspected hypersensitivity to quinolones, mometasone furoate monohydrate, or posaconazole. Do not use in dogs with known tympanic perforation (see **PRECAUTIONS**).

WARNINGS:

Human Warnings: Not for use in humans. Keep out of reach of children.

Animal Warnings: Do not administer orally. Immediately discontinue use of POSATEX™ Otic Suspension if hearing loss is observed during treatment (see **ADVERSE REACTIONS**).

PRECAUTIONS: The use of POSATEX™ Otic Suspension in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membranes should be confirmed before administering this product.

Avoid prolonged or repeated use of POSATEX™ Otic Suspension. Long-term use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **ANIMAL SAFETY**). The safe use of POSATEX™ Otic Suspension in dogs used for breeding purposes, during pregnancy or in lactating bitches, has not been evaluated. The systemic administration of quinolones has been shown to produce cartilage erosions of weight bearing joints and other signs of arthropathy in immature animals of various species.

ADVERSE REACTIONS: In the field study, 143 dogs were treated with POSATEX™ Otic Suspension. Of those, 1 dog with bilateral otitis externa developed hearing loss. POSATEX™ Otic Suspension treatment was discontinued and the condition resolved after one week.

To report suspected adverse reactions, call 1-800-224-5318.

For a copy of the Material Safety Data Sheet (MSDS) call 1-800-770-8878.

CLINICAL PHARMACOLOGY:

Orbifloxacin: Orbifloxacin is a synthetic fluoroquinolone antibacterial agent. The bactericidal action of fluoroquinolones is concentration-dependent and results from interference with bacterial DNA gyrase and topoisomerase IV. Since these enzymes are needed for bacterial DNA synthesis and transcription, fluoroquinolones disrupt bacterial replication and lead to bacterial cell death.

Mometasone: Mometasone furoate monohydrate is a topical corticosteroid characterized by a (2') furoate 17-ester having chlorine at the 9 and 21 positions.

Posaconazole: Posaconazole is a broad-spectrum triazole antifungal agent. The mechanism by which triazoles exert fungicidal action involves the selective inhibition of the enzyme lanosterol a C14 demethylase (a microsomal cytochrome P-450- dependent enzyme) involved in ergosterol biosynthesis in yeasts and filamentous fungi.

Systemic absorption of the active ingredients was determined in single-dose radiolabelled studies with ¹⁴C-orbifloxacin, ³H-mometasone furoate, and ¹⁴C-posaconazole contained within the POSATEX™ Otic Suspension formulation and placed into the ear canals of normal beagle dogs. Most of the absorption occurred in the first few days after administration. The extent of percutaneous absorption of topical medications is influenced by many factors including the integrity of the epidermal barrier. Inflammation can increase the percutaneous absorption of drugs.

EFFECTIVENESS: The effectiveness of POSATEX™ Otic Suspension was evaluated in a placebo-controlled, double-blind, multi-site field study. One hundred and ninety one dogs with naturally occurring clinical otitis externa associated with both yeast and bacteria were randomly allocated to either POSATEX™ Otic Suspension or placebo ointment. Of the 160 dogs evaluated for effectiveness, 122 were treated with POSATEX™ Otic Suspension and 38 were treated with placebo ointment. Treatments were administered once daily for 7 consecutive days. Assessment of effectiveness was based on improvement in clinical signs at re-evaluation 2-7 days following administration of the last dose. Compared to the placebo, a significant percent of dogs treated with POSATEX™ Otic Suspension showed improvement in clinical signs (discomfort, erythema, and swelling) caused by otitis externa associated with one or more of the following organisms: *Malassezia pachydermatis*, coagulase positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*.

Percent of Dogs Showing Improvement in Clinical Signs of Otitis Externa

| Clinical Sign | POSATEX® Otic Suspension Group | Placebo Group | Significance |
|-----------------------------|--------------------------------|---------------|--------------|
| Discomfort | 88% | 45% | p<0.0001 |
| External Ear Canal Erythema | 81% | 39% | p<0.0001 |
| External Ear Canal Swelling | 83% | 49% | p<0.0001 |

ANIMAL SAFETY: POSATEX™ Otic Suspension was administered at 1,3, and 5 times the recommended dosage for 21 consecutive days. The control group received the vehicle in both ears at the clinical dose given five times per day. There was a slight decrease in serum cortisol concentration after ACTH stimulation on Day 21 in the 5X group. Erythema was noted in all groups. Aural pain, swelling, or heat were each noted in 3 separate dogs in the 5X group.

STORAGE INFORMATION: Store at temperatures between 2°-30°C (35.6°-86°F).

Shake well before use.

HOW SUPPLIED: POSATEX™ Otic Suspension is available in 7.5 g, 15 g, and 30 g plastic bottles.

NADA# 141-266, Approved by FDA.

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Summit, NJ 07901 USA

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Made in Germany

POSATEX[®] treats a broad range of otitis externa cases with its **highly effective** and reliable ingredients to keep pets healthy.

- Studies show its effectiveness against even the most stubborn cases of otitis externa¹
- It is effective against the three most common pathogens in otitis externa¹
- Stability evidenced in the face of ear cleaners (which are recommended prior to treatment)¹
- Outstanding safety and efficacy has been proven in field trials and years of use

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For technical support, call Merck Animal Health

CUSTOMER SERVICE (MON.-FRI., 8:30 AM-7 PM, ET): 1-800-521-5767

TECHNICAL SERVICE (MON.-FRI., 8:30 AM-5 PM, ET): 1-800-224-5318

www.merck-animal-health-usa.com

References

1. Data on file at Merck Animal Health.
2. Freedom of Information Summary. Original New Animal Drug Application (NADA 141-266). POSATEX Otic Suspension. Summit, NJ: Intervet Inc. Feb. 18, 2010.

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