POSATEX- orbifloxacin, mometasone furoate, and posaconazole suspension
Merck Sharp & Dohme Corp.

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 ^{14}C-orbifloxacin, ^{3}H-mometasone furoate, and ^{14}C-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 5× group. Erythema was noted in all groups. Aural pain, swelling, or heat were each noted in 3 separate dogs in the 5× 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.

Made in Germany

Rev. 06/2018

187045 R2

PRINCIPAL DISPLAY PANEL - 30 g Bottle Label

NDC 0061-0089-03
30g

Posatex®
Otic Suspension

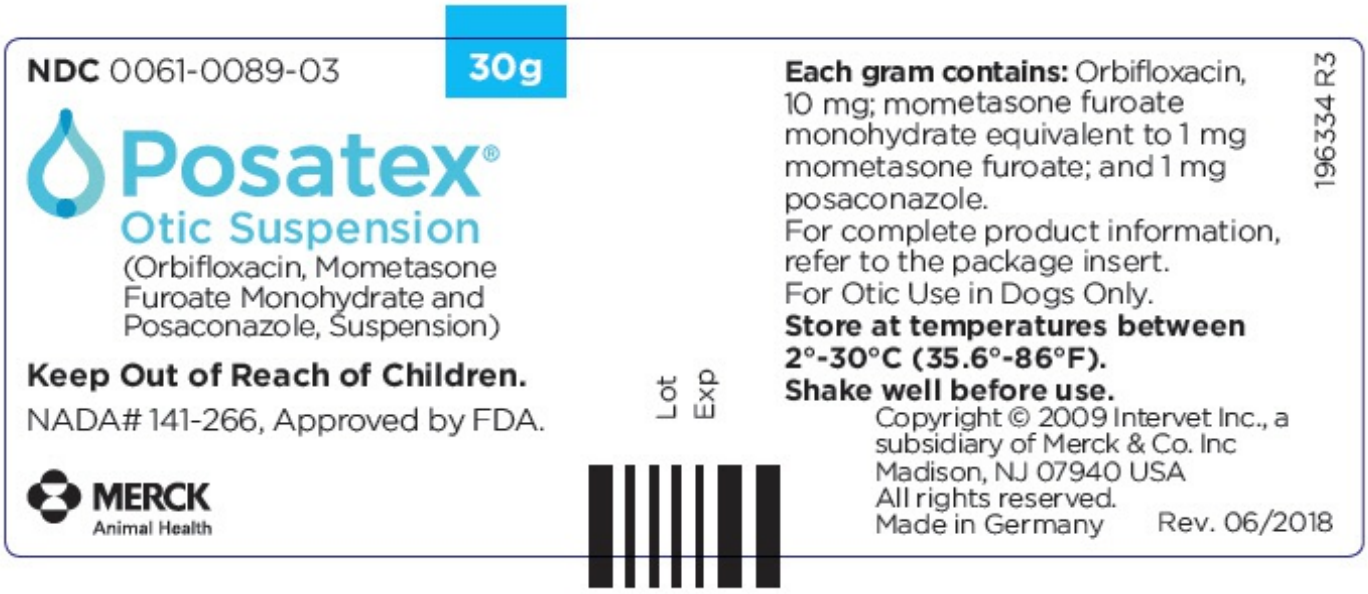
(Orbifloxacin, Mometasone
Furoate Monohydrate and
Posaconazole, Suspension)

Keep Out of Reach of Children.

-

NADA# 141-266, Approved by FDA.

MERCK
Animal Health



POSATEX

orbifloxacin, mometasone furoate, and posaconazole suspension

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0061-0089
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Orbifloxacin (UNII: 660932TPY6) (Orbifloxacin - UNII:660932TPY6)	Orbifloxacin	10 mg in 1 g
Mometasone Furoate (UNII: 04201GDN4R) (Mometasone - UNII:8HR4QJ6DW8)	Mometasone Furoate	1 mg in 1 g
posaconazole (UNII: 6TK1G07BHZ) (posaconazole - UNII:6TK1G07BHZ)	posaconazole	1 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Mineral Oil (UNII: T5L8T28FGP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0061-0089-01	1 in 1 CARTON		
1		7.5 g in 1 BOTTLE, PLASTIC		

2	NDC:0061-0089-02	1 in 1 CARTON		
2		15 g in 1 BOTTLE, PLASTIC		
3	NDC:0061-0089-03	1 in 1 CARTON		
3		30 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141266	02/18/2020	

Labeler - Merck Sharp & Dohme Corp. (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
Vet Pharma Friesoythe GmbH		341934053	MANUFACTURE, ANALYSIS

Revised: 3/2022 Merck Sharp & Dohme Corp.