PATTOTIC- gentamicin sulfate, mometasone furoate monohydrate, and clotrimazole suspension
Patterson Veterinary

PattOtic™
(GENTAMICIN SULFATE, USP;
MOMETASONE FUROATE
MONOHYDRATE;
AND CLOTRIMAZOLE, USP,
OTIC SUSPENSION)

F-27078915
NADA #141-177, Approved by FDA.

PRODUCT
INFORMATION

VETERINARY
For Otic Use in Dogs Only

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

Keep this and all drugs out of the reach of children.

DESCRIPTION Each gram of PattOtic™ Otic Suspension contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base; mometasone furoate monohydrate equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP in a mineral oilbased system containing a plasticized hydrocarbon gel.

PHARMACOLOGY

Gentamicin: Gentamicin sulfate is an aminoglycoside antibiotic active against a wide variety of gram-negative and grampositive bacteria. *In vitro* tests have determined that gentamicin is bactericidal and acts by inhibiting normal protein synthesis in susceptible microorganisms. In clinical trials, gentamicin was shown to have a range of activity against the following organisms commonly isolated from infected canine ears:

Pseudomonas spp. (including *P. aeruginosa*), coagulasepositive staphylococci, *Enterococcus faecalis, Proteus mirabilis* and beta-hemolytic streptococci.

Mometasone: Mometasone furoate monohydrate is a synthetic adrenocorticoid characterized by a novel (2') furoate 17-ester having chlorine at the 9 and 21 positions, which have shown to possess high topical potency.

Systemic absorption of mometasone furoate ointment was found to be minimal (2%) over 1 week when applied topically to dogs with intact skin. In a 6-month dermal toxicity study using 0.1% mometasone ointment on healthy intact skin in dogs, systemic effects typical of corticosteroid therapy were noted.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the integrity of the epidermal barrier. Topical corticosteroids can be absorbed from normal, intact skin. Inflammation can increase percutaneous absorption. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids.

Clotrimazole: Clotrimazole is a broad-spectrum antifungal agent that is used for the treatment of dermal infections caused by various species of dermatophytes and yeast. The primary action of clotrimazole is against dividing and growing organisms.

In vitro, clotrimazole exhibits fungistatic and fungicidal activity against isolates of *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, Microsporum canis, Candida* spp., and

Malassezia pachydermatis. Resistance to clotrimazole is very rare among the fungi that cause superficial mycoses. In an induced otitis externa study using dogs infected with *Malassezia pachydermatis*, 1% clotrimazole in the vehicle formulation was effective both microbiologically and clinically in terms of reduction of exudate, odor, and swelling.

In studies of the mechanism of action, the minimum fungicidal concentration of clotrimazole caused leakage of intracellular phosphorus compounds into the ambient medium with concomitant breakdown of cellular nucleic acids and accelerated potassium efflux. These events began rapidly and extensively after addition of the drug. Clotrimazole is very poorly absorbed following dermal application.

Gentamicin-Mometasone-Clotrimazole: By virtue of its three active ingredients, PattOtic Otic Suspension has antibacterial, anti-inflammatory, and antifungal activity. In clinical field trials, PattOtic Otic Suspension was effective in the treatment of otitis externa associated with bacteria and Malassezia pachydermatis. PattOtic Otic Suspension reduced discomfort, redness, swelling, exudate, and odor.

INDICATIONS PattOtic Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulasepositive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

CONTRAINDICATIONS If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. Concomitant use of drugs known to induce ototoxicity should be avoided. Do not use in dogs with known perforation of eardrums.

WARNINGS The use of these components has been associated with deafness or partial hearing loss in a small number of sensitive dogs (eg, geriatric). The hearing deficit is usually temporary. If hearing or vestibular dysfunction is noted during the course of treatment, discontinue use of PattOtic Otic Suspension immediately and flush the ear canal thoroughly with a nonototoxic solution.

Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs that received corticosteroids during pregnancy.

Field and experimental data have demonstrated that corticostroids administered orally or parenterally to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

PRECAUTIONS 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.

Administration of recommended doses of PattOtic Otic Suspension beyond 7 days may result in delayed wound healing. If overgrowth of nonsusceptible bacteria or fungi occurs, treatment should be discontinued and appropriate therapy instituted.

Avoid ingestion. Adverse systemic reactions have been observed following the oral ingestion of some topical corticosteroid preparations. Patients should be closely observed for the usual signs of adrenocorticoid overdosage which include 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.

TOXICOLOGY Field and safety studies with PattOtic Otic Suspension have shown a wide safety margin at the recommended dose level in dogs (see **PRECAUTIONS/ADVERSE REACTIONS**).

ADVERSE REACTIONS

Gentamicin: While aminoglycosides are absorbed poorly from skin, intoxication may occur when aminoglycosides are applied topically for prolonged periods of time to large wounds, burns, or any denuded skin, particularly if there is renal insufficiency. All aminoglycosides have the potential to produce reversible and irreversible vestibular, cochlear, and renal toxicity.

Mometasone: ALP (SAP) and ALT (SGPT) enzyme elevations, weight loss, anorexia, polydipsia, polyuria, neutrophilia, and lymphopenia have occurred following the use of parenteral, high-dose, and/or prolonged or systemic synthetic corticosteroids in dogs. Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

Clotrimazole: The following have been reported occasionally in humans in connection with the use of clotrimazole: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin not present before therapy.

PattOtic Otic Suspension: In field studies following once daily teatment with PattOtic Otic Suspension, ataxia, proprioceptive deficits, and increased water consumption were observed in less than 1% of 164 dogs. In a field study following twice-daily treatment with PattOtic Otic Suspension, inflammation of the pinna and diarrhea were observed in less than 1% of 141 dogs.

DOSAGE AND ADMINISTRATION

The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops from the 7.5 g, 15 g, and 30 g bottles (2 drops from the 215 g bottle) of PattOtic Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the 7.5 g, 15 g, and 30 g bottles (4 drops from the 215 g bottle) once daily into the ear canal. Therapy should continue for 7 consecutive days.

HOW SUPPLIED PattOtic Otic Suspension is available in 7.5 g (NDC 14043-125-75), 15 g (NDC 14043-115-15), 30 g (NDC 14043-120-30), and 215 g (NDC 14043-130-21) plastic bottles.

Store between 2° and 25°C (36° and 77°F). Shake well before use.

U.S. Patent No. 6,127,353.

Distributed by
PATTERSON VETERINARY
137 Barnum Road, Devens, MA 01434
www.pattersonvet.com

Made in Canada.
9/15

81-261201

PRINCIPAL DISPLAY PANEL - 15 g Bottle Carton

NDC #14043-115-15

PATTERSON®
VETERINARY

1-800-225-7911

PattOtic™
Otic Suspension

(Gentamicin Sulfate, USP;
Mometasone Furoate
Monohydrate;

and Clotrimazole, USP,
Otic Suspension)

For otic use
in dogs only.

Keep Out of Reach
of Children.

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

Net Contents: 15 g

NADA #141-177, Approved by FDA

304

NDC #14043-115-15

PATTERSON VETERINARY
1-800-225-7911

PattOtic™
Otic Suspension

(Gentamicin Sulfate, USP;
Mometasone Furoate
Monohydrate;
and Clotrimazole, USP,
Otic Suspension)

For otic use in dogs only.

Keep Out of Reach of Children.

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

Net Contents: 15 g

NADA #141-177, Approved by FDA

PATTERSON VETERINARY
1-800-225-7911

PattOtic™
Otic Suspension
(Gentamicin Sulfate, USP;
Mometasone Furoate
Monohydrate;
and Clotrimazole, USP,
Otic Suspension)

For otic use in dogs only.

NON VERNI • NO VARNISH • NON VERN

ISH • NON VERNI • NO VARNISH • NO

304

NON VERNI • NO VARNISH • NON VERN

ISH • NON VERNI • NO VARNISH • NO

For otic use in dogs only.

(Gentamicin Sulfate, USP; Mometasone Furoate Monohydrate; and Clotrimazole, USP, Otic Suspension)

PattOtic™

WSH307D3-V2

NDC #14043-115-15

PATTERSON VETERINARY

1-800-225-7911

PattOtic™

Otic Suspension

For otic use in dogs only.

Indications: PattOtic™ Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis, Proteus mirabilis*, and beta-hemolytic streptococci).

Description: Each gram of **PattOtic** Otic Suspension contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base; mometasone furoate monohydrate equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP in a mineral oil-based system containing a plasticized hydrocarbon gel.

Dosage and Administration: The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops from the bottle of **PattOtic** Otic Suspension once daily into the earcanal. For dogs weighing 30 lbs or more, instill 8 drops from the bottle once daily into the ear canal. Therapy should continue for 7 consecutive days.

PATTERSON VETERINARY

1-800-225-7911

PattOtic™

Otic Suspension

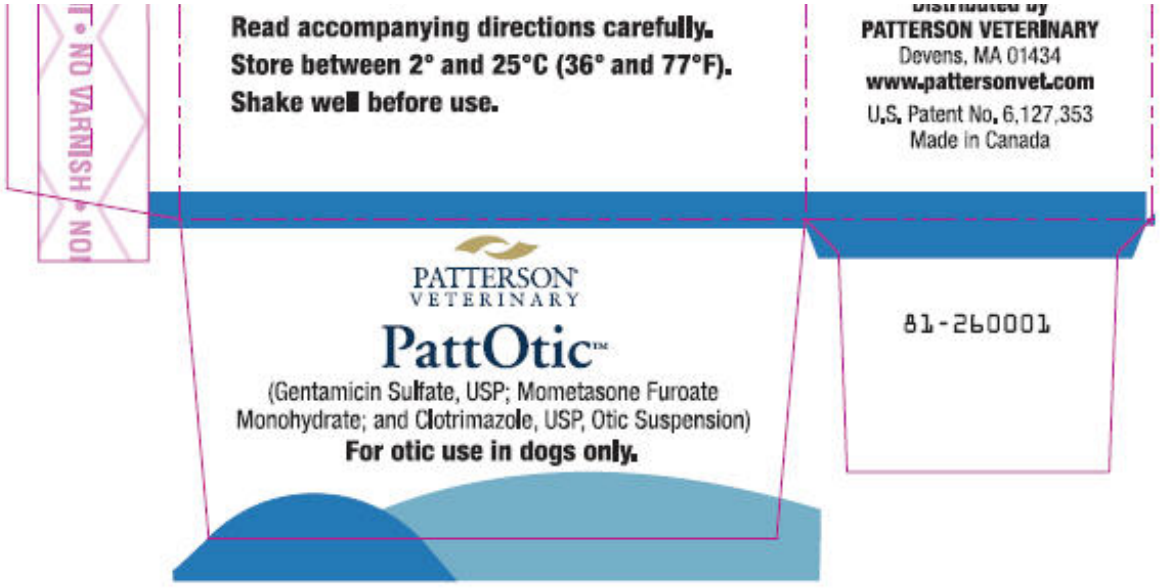
(Gentamicin Sulfate, USP; Mometasone Furoate Monohydrate; and Clotrimazole, USP, Otic Suspension)

For otic use in dogs only.

Reorder #07-8921500

8 89215 00001 8

Distributed by



PATTOTIC

gentamicin sulfate, mometasone furoate monohydrate, and clotrimazole suspension

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:14043-115
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Gentamicin Sulfate (UNII: 8X7386QRLV) (Gentamicin - UNII:T6Z9V48IKG)	Gentamicin	3 mg in 1 g
Mometasone Furoate Monohydrate (UNII: MTW0WEG809) (Mometasone - UNII:8HR4QJ6DW8)	Mometasone Furoate	1 mg in 1 g
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	10 mg in 1 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:14043-115-15	1 in 1 CARTON		
1		15 g in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141177	02/01/2016	

Labeler - Patterson Veterinary (006962500)

Revised: 11/2015 Patterson Veterinary