

ZN4.5 OTIC- zinc gluconate solution

H&C Animal Health

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Zn4.5 Otic

INDICATIONS:

A natural, complexed zinc and amino acid, non-staining ear care formula for pets. Helps eliminate odor-causing bacteria. Nourishes and replenishes the ear tissue.

- Natural Complexed Zinc and Amino Acid formula.
- Creates a Healthy Environment in the Ear.
- Non-Staining
- Safe for Daily Use

Keep out of reach of children.

DIRECTIONS:

Fill cleansed ear canal with Zn4.5Otic, massage base of ear canal. Subsequent applications, apply 5-8 drops daily. If irritation increases, discontinue use and consult your veterinarian. Regular ear exams by veterinarian is recommended.

MAINTENANCE:

Apply product as above 2-3 times per week. Ears should be regularly evaluated by a veterinarian.

INGREDIENTS:

Deionized Water, Zinc Gluconate, Boric Acid, L-Lysine, Propylene Glycol, Taurine, Methylparaben, Propylparaben.

DISTRIBUTED BY H&C ANIMAL HEALTH , LLC.

MADE IN THE U.S.A.

Addison Biological Laboratory, Inc.

507 North Cleveland Avenue
Fayette, Missouri 65248 U.S.A.

www.addisonlabs.com

Rev. 04/20

Package label, display panel

MAXI/GUARD®

Zn4.5Otic®

- Natural Complexed Zinc and Amino Acid formula.
- Creates a Healthy Environment in the Ear.
- Non-Staining

- Safe for Daily Use

2 FL. OZ. (59mL)

FEATURES:

A natural, complexed zinc and amino acid, non-staining ear care formula for pets. Helps eliminate odor-causing bacteria. Nourishes and replenishes the ear tissue. Nourishes and replenishes

DIRECTIONS:

Fill cleansed ear canal with Zn4.5Otic, massage base of ear canal. Subsequent applications, apply 5-8 drops daily. If irritation increases, discontinue use and consult your veterinarian. Regular ear exams by veterinarian is recommended.

MAINTENANCE:

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INGREDIENTS:

Deionized Water, Zinc Gluconate, Boric Acid, L-Lysine, Propylene Glycol, Taurine, Methylparaben, Propylparaben.

KEEP OUT OF REACH OF CHILDREN.

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Rev. 04/20



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		FILE NAME <u>MAXIGUARD/ADDLAB-32120</u> VENDOR <u>ADDISON LABS</u>
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Package label , display panel

MAXI/GUARD®

Zn4.5Otic®

- Natural Complexed Zinc and Amino Acid formula.
- Creates a Healthy Environment in the Ear.
- Non-Staining
- Safe for Daily Use

4 FL. OZ. (118mL)

FEATURES:

A natural, complexed zinc and amino acid, non-staining ear care formula for pets. Helps eliminate odor-causing bacteria. Nourishes and replenishes the ear tissue. Nourishes and replenishes

DIRECTIONS:

Fill cleansed ear canal with Zn4.5Otic, massage base of ear canal. Subsequent applications, apply 5-8 drops daily. If irritation increases, discontinue use and consult your veterinarian. Regular ear exams by veterinarian is recommended.

MAINTENANCE:

Apply product as above 2-3 times per week. Ears should be regularly evaluated by a veterinarian.

INGREDIENTS:

Deionized Water, Zinc Gluconate, Boric Acid,
L-Lysine, Propylene Glycol,
Taurine, Methylparaben, Propylparaben.

KEEP OUT OF REACH OF CHILDREN.

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PROOF APPROVAL CHECKLIST Please Check All That Apply

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	1 THIS WAY <input type="checkbox"/> 2 TURN STILL <input type="checkbox"/> 3 THIS WAY <input type="checkbox"/> 4 THIS WAY <input checked="" type="checkbox"/> 5 THIS WAY <input type="checkbox"/> 6 TURN STILL <input type="checkbox"/> 7 THIS WAY <input type="checkbox"/> 8 TURN STILL <input type="checkbox"/>	FILE NAME <u>MAXIGUSR/ADDLAB-32121</u> VENDOR <u>ADDISON LABS</u>
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ZN4.5 OTIC

zinc gluconate solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86137-7609
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	.011 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TAURINE (UNII: 1EQV5MLY3D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LYSINE (UNII: K3Z4F929H6)	
BORIC ACID (UNII: R5Z7HV85D4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86137-7609-0	59 mL in 1 PACKAGE		
2	NDC:86137-7609-1	118 mL in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2021	

Labeler - H&C Animal Health (080739405)

Registrant - Addison Biological Laboratory, Inc. (118396730)

Establishment

Name	Address	ID/FEI	Business Operations
Addison Biological Laboratory, Inc.		118396730	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
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Jost Chemical Co.		147882294	api manufacture
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Establishment

Name	Address	ID/FEI	Business Operations
Alliance Analytical Laboratories, Inc.		007588338	analysis

Establishment

Name	Address	ID/FEI	Business Operations
ADAMSON ANALYTICAL LABORATORIES INC		944399906	analysis

Revised: 11/2023

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