

ZN4.5OTIC- zinc gluconate solution
Addison Biological Laboratory, Inc.

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.

Zn4.5Otic®

INDICATIONS:

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

Complexed zinc and amino acid formula.

Keep out of reach of children.

DIRECTIONS:

Cleanse ear canal with suitable cleanser. Fill ear canal with Zn4.5Otic, massage base of ear canal. For subsequent applications, apply 5-8 drops daily. If undue irritation develops or increases, discontinue use and consult your veterinarian.

MAINTENANCE:

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

INGREDIENTS:

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

Addison Biological Laboratory, Inc.
507 North Cleveland Avenue
Fayette, Missouri 65248 U.S.A.
www.addisonlabs.com
MADE IN THE U.S.A.
Rev. 05/13

MAXI/GUARD®

Zn4.5Otic®

A Natural
Ear Care Solution
Delivering
Complexed Zinc™
1 FL. OZ. (29.5mL)

INDICATIONS:

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

acid formula.

Keep out of reach of children.

DIRECTIONS:

Cleanse ear canal with suitable cleanser.

Fill ear canal with Zn4.5Otic®, massage base of ear canal. For subsequent applications, apply 5-8 drops daily. If undue irritation develops or increases, discontinue use and consult your veterinarian.

MAINTENANCE:

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

INGREDIENTS:

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

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MADE IN THE U.S.A.

Rev. 06/19



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MATERIAL IS CORRECT ☐ SIZE LISTED IS CORRECT ☐ UPC IS CORRECT ☐ SPELLING IS CORRECT ☐ COLORS ARE CORRECT ☐ WIND DIRECTION CORRECT ☐

CYAN	MAG	YELO	BLACK	JETRION	INDIGO	FLEXO	SIZE <u>1.5 X 3.625</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SUBSTRATE <u>BOPP</u>
							ADHESIVE <u>PERMANENT</u>
							FILE NAME <u>ADDLAB-18441</u> VENDOR <u>ADDISON LABS</u>
YOUR SIGNED APPROVAL IS REQUIRED FOR US TO PROCEED. BY SIGNING, YOU ASSUME RESPONSIBILITY FOR THE ACCURACY OF THIS PROOF.							AS SUBMITTED/signature&date <input type="checkbox"/> YES <input type="checkbox"/> NO
							Date: 06/25/19 46777 Proof #4

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MAXI/GUARD®
Zn_{4.5}Otic®

A Natural
Ear Care Solution
Delivering
Complexed Zinc™
2 FL. OZ. (59mL)

INDICATIONS:

A natural, complexed zinc,
non-staining ear care formula
for pets. Helps eliminate
odor-causing bacteria.

Nourishes and replenishes
the ear epithelium.

Complexed zinc and amino
acid formula.

Keep out of reach of children.

DIRECTIONS:

Cleanse ear canal with suitable cleanser.

Fill ear canal with Zn4.5Otic®, massage
base of ear canal. For subsequent
applications, apply 5-8 drops daily. If
undue irritation develops or increases,
discontinue use and consult your
veterinarian.

MAINTENANCE:

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

INGREDIENTS:

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

Addison Biological Laboratory, Inc.

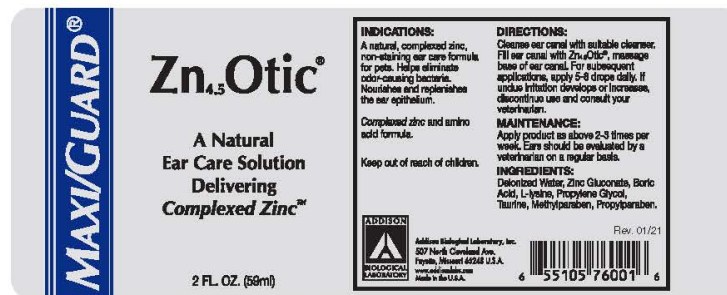
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Pantone 287 Pantone BLACK		JETRION <input type="checkbox"/> INDIGO <input type="checkbox"/> FLEXO <input checked="" type="checkbox"/>	SIZE 1.75 X 4.375 SUBSTRATE BOPP ADHESIVE PERMANENT
1 THIS WAY 2 AWM STILL 3 THIS WAY 4 5 THIS WAY 6 AWM STILL 7 THIS WAY 8		FILE NAME ADDLAB-14066 VENDOR ADDISON LABS	
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MAXI/GUARD®
Zn_{4.5}Otic®

A Natural
Ear Care Solution
Delivering
Complexed Zinc™
4 FL. OZ. 118mL)

INDICATIONS:

A natural, complexed zinc,
non-staining ear care formula
for pets. Helps eliminate
odor-causing bacteria.

Nourishes and replenishes
the ear epithelium.

Complexed zinc and amino
acid formula.

Keep out of reach of children.

DIRECTIONS:

Cleanse ear canal with suitable cleanser.

Fill ear canal with Zn4.5Otic®, massage
base of ear canal. For subsequent
applications, apply 5-8 drops daily. If
undue irritation develops or increases,
discontinue use and consult your
veterinarian.

MAINTENANCE:

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

INGREDIENTS:

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

Addison Biological Laboratory, Inc.

507 North Cleveland Avenue

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PROOF APPROVAL CHECKLIST Please Check All That Apply

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<div> <div>Pantone 287</div> <div>Pantone BLACK</div> </div>	<div> <div>JETRON</div> <div>INDIGO</div> <div>FLEXO</div> </div>	<div> <div>SIZE</div> <div>2.625 X 5.375</div> </div>
	<div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input checked="" type="checkbox"/></div> </div>	<div> <div>SUBSTRATE</div> <div>BOPP</div> </div>
		<div> <div>ADHESIVE</div> <div>PERMANENT</div> </div>
<div> <div>1 THIS WAY</div> <div>2 AVOID STICK</div> <div>3 AVOID STICK</div> <div>4 AVOID STICK</div> <div>5 THIS WAY</div> <div>6 AVOID STICK</div> <div>7 AVOID STICK</div> <div>8 AVOID STICK</div> </div>	<div> <div>FILE NAME</div> <div>ADDLAB-14083</div> </div>	<div> <div>ATJ</div> <div>DW</div> </div>
<div> <div>VENDOR</div> <div>ADDISON LABS</div> </div>	<div> <div>YOUR SIGNED APP ROVAL IS REQUIRED FOR US TO PROCEED. BY SIGNING, YOU ASSUME RESPONSIBILITY FOR THE ACCURACY OF THIS PROOF.</div> <div> <div>AS SUBMITTED/signature&date</div> <div> <div>YES</div> <div>NO</div> </div> </div> </div>	
<div> <div>Date: 08/03/17</div> <div>23732</div> </div>		<div> <div>Proof #1</div> </div>

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ZN4.5OTIC

zinc gluconate solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86045-5000
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: R57ZHV85D4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86045-5000-2	59 mL in 1 PACKAGE		
2	NDC:86045-5000-3	118 mL in 1 PACKAGE		
3	NDC:86045-5000-1	29.5 mL in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2003	

Labeler - Addison Biological Laboratory, Inc. (118396730)

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
Jost Chemical Co.		147882294	api manufacture

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

Addison Biological Laboratory, Inc.