#### ORAZN- zinc gluconate gel 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.

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# OraZn

**Features:** Easy applicator tip, taste free formulation, and neutralized zinc cleansing.

**Benefits:** Natural oral cleansing without brushing, instant fresh breath, and superior pet acceptance.

**Directions:** Apply gel directly to the outside gums above the back upper molars. One drop placed on your index finger, swab, or fingerbrush and applied on each side of the mouth will provide optimum pet acceptance in adult cats. Use slightly more for small dogs. Most medium to large dogs will accept direct application from the built-in applicator tip. A natural cleansing action will distribute the gel to remote areas of the mouth. Use daily for best results.

**Storage:** Store at room temperature and keep out of direct sunlight.

**Ingredients:** Deionized water, Carboxymethylcellulose, Zinc gluconate, Taurine, Methylparaben, Propylparaben, F.D.&C. Blue #1.

# Keep out of reach of children.

Addison Biological Laboratory, Inc.

507 North Cleveland Avenue

Fayette, Missouri 65248 U.S.A.

www.addisonlabs.com

MADE IN THE U.S.A.

Rev. 06/17

## Principle Display Panel - OraZn

Cleanses & Freshens Without Brushing **OraZn®** Pet Oral Care

Neutralized Zinc

- Taste Free
- Natural Formula

# 2 FL. OZ (59ml)

### MAXI/GUARD®

**Features:** Easy applicator tip, taste free formulation, and neutralized zinc cleansing. **Benefits:** Natural oral cleansing without brushing, instant fresh breath, and superior pet acceptance.

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Addison Biological Laboratory, Inc. 507 North Cleveland Avenue Fayette, Missouri 65248 U.S.A. www.addisonlabs.com MADE IN THE U.S.A. Rev. 06/17





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#### ORAZN

Product Information         Product Type       OTC ANIMAL DRUG       NDC:86045-3300         Route of Administration       ORAL         Active Ingredient/Active Moiety         Ingredient Name       Basis of Strength       Strength         Ingredient Name       Basis of Strength       Strength         Ingredient Name       Ingredients         Ingredient Name       Strength         Ingredient Name       Strength         Ingredients         Ingredient Name       Strength         METHYLPARABEN (UNII: 259050K00R)         TAURINE (UNII: 160/S060K00R)       Strength         TAURINE (UNII: 2818/25/101)       Strength         PROPYLPARABEN (UNII: 2818/25/2107)       Strength         Packaging         #       them Code       Package Description       Marketing Start Date       Marketing End Date         1       Strength       Strength         Marketing Information       Strength       Strength <td colsp<="" th=""><th>zinc gluconate gel</th><th></th><th></th><th></th><th></th><th></th><th></th></td>	<th>zinc gluconate gel</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>	zinc gluconate gel						
Product Type Route of Administration       OTC ANIMAL DRUG ORAL       Item Code (Source)       NDC:86045-3300         Active Ingredient/Active Moiety         Ingredient Name       Basis of Strength       Strength         Ingredient Name       Basis of Strength       Strength         Ingredient Name       Basis of Strength         Ingredient Name       Basis of Strength         Ingredients       .0165 g in 1 m         Ingredient Name       Strength         Ingredient Name       Strength         Ingredients       .0165 g in 1 m         Ingredient Name       Strength         PROPUPARABEN (UNII: 269QF0KO0R)       Ingredient Name       Strength         FROPYLPARABEN (UNII: 281225C10H)       FOOPLPARABEN (UNII: 281225C10H)         FOOPLPARABEN (UNII: 281225C10H)       FOOPLPARABEN (UNII: 281225C10H)         FOOPLPARABEN (UNII: 281225C10H)       FOOPLPARABEN (UNII: 281225C10H)         FOOPLPARABEN (UNII: 18347K3TBD)       CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)         Inten Code Package Description Marketing Start Date <td colsp<="" th=""><th>Product Informa</th><th>tion</th><th></th><th></th><th></th><th></th><th></th></td>	<th>Product Informa</th> <th>tion</th> <th></th> <th></th> <th></th> <th></th> <th></th>	Product Informa	tion					
Active of Administration       ORAL         Active Ingredient/Active Moiety         Ingredient Name       Basis of Strength       Strength         ZINC GLUCONATE (UNII: UGWS/N5SQ1Z) (ZINC CATION - UNII: 1351585F37)       ZINC GLUCONATE       .0165 g in 1 m         Inactive Ingredients         Ingredient Name       Strength         Marter (UNII: 059QF0K00R)         TAURINE (UNII: 2602F0K00R)         TAURINE (UNII: 2802F0K00R)         TAURINE (UNII: 2802F0K00R)         TAURINE (UNII: 2802F0K00R)         TAURINE (UNII: 2802F0K00R)         TAURINE (UNII: 2802F0H0T)         PROPYLPARABEN (UNII: 2802F0H0T)         PROPYLPARABEN (UNII: 2802F0H0T)         PACKaging         # Item Code       Package Description       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       Symmetion 12 in 1 BOX       Marketing Information         Marketing Information       Marketing Category       Application Number or Monograph       Marketing Start       Marketing End Date								
Active Ingredient/Active Moiety         Ingredient Name       Basis of Strength       Strength         ZINC GLUCONATE (UNII: UGWSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)       ZINC GLUCONATE       .0165 g in 1 m         Inactive Ingredients       Strength         Ingredient Name       Strength         Marter (UNII: 059QF0K00R)       Strength         TAURINE (UNII: 1EQV5MLY3D)       Strength         METHYLPARABEN (UNII: 2812S2C10H)       FOGC BLUE NO. 1 (UNII: 13847K3TBD)         FOGC BLUE NO. 1 (UNII: 3847K3TBD)       CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)         Packaging         # Item Code Package Description Marketing Start Date Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       S         The Strength Marketing Start Date Marketing End Date         Marketing Information         Marketing Start Date Marketing End Date         Marketing Category       Application Number or Monograph Date       Marketing Start Marketing End Date	Product Type		OTC ANIMAL DRUG	ltem Co	de (Source)	NDC:	86045-3300	
Ingredient Name       Basis of Strength       Strength         ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S158SF37)       ZINC GLUCONATE       .0165 g in 1 m         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         WATER (UNII: 059QF0K00R)       Ingredient Name       Strength         TAURINE (UNII: 1EQV5MLY3D)       Ingredient Name       Strength         METHYLPARABEN (UNII: 28IX2SC10H)       PROPYLPARABEN (UNII: 28IX2SC10H)       Ingredient State Name       Ingredient Name         Packaging       Ingredient Name       Ingredient Name       Ingredient Name       Ingredient Name         Marketing Information       Ingredient Name       Ingredient Name       Ingredient Name       Ingredient Name         Marketing       Application Number or Monograph       Marketing Start       Marketing End Date         Unapproved drug       Information       Ingredient Name       Ingredient Name       Ingredient Name	Route of Administr	ation	ORAL					
Ingredient Name       Basis of Strength       Strength         ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S158SF37)       ZINC GLUCONATE       .0165 g in 1 m         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         WATER (UNII: 059QF0K00R)       Ingredient Name       Strength         TAURINE (UNII: 1EQV5MLY3D)       Ingredient Name       Strength         METHYLPARABEN (UNII: 28IX2SC10H)       PROPYLPARABEN (UNII: 28IX2SC10H)       Ingredient State Name       Ingredient Name         Packaging       Ingredient Name       Ingredient Name       Ingredient Name       Ingredient Name         Marketing Information       Ingredient Name       Ingredient Name       Ingredient Name       Ingredient Name         Marketing       Application Number or Monograph       Marketing Start       Marketing End Date         Unapproved drug       Information       Ingredient Name       Ingredient Name       Ingredient Name								
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S158SF37) ZINC GLUCONATE .0165 g in 1 m Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0K00R) TAURINE (UNII: 15QV5MLY3D) METHYLPARABEN (UNII: 28IX2SC10H) PROPYLPARABEN (UNII: 28IX2SC10H) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X) PACKaging I tem Code Package Description Marketing Start Date Marketing End Date 1 NDC:86045-3300-1 12 in 1 BOX 1 59 mL in 1 BOTTLE Marketing Information Marketing Application Number or Monograph Marketing Start Marketing End Date Unapproved drug 01/01/2001	Active Ingredien		-					
Ingredients         Ingredient Name       Strength         WATER (UNII: 059QF0K00R)         TAURINE (UNII: 1EQV5MLY3D)         METHYLPARABEN (UNII: A218C7H19T)         POPYLPARABEN (UNII: 281X2SC10H)         FD&C BLUE NO. 1 (UNII: B3R47K3TBD)         CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       1       1       1         Sp mL in 1 BOTTLE		-				-	-	
Ingredient Name       Strength         WATER (UNII: 059QF0K00R)         TAURINE (UNII: 1EQV5MLY3D)         METHYLPARABEN (UNII: A218C7H19T)         PROPYLPARABEN (UNII: 281X2SC10H)         FD&C BLUE NO. 1 (UNII: H3R47K3TBD)         CARBOXYMETHYLCELULOSE (UNII: 05JZ17B19X)         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       1       1       1         S	ZINC GLUCONATE (UN	II: U6WSN5S	Q1Z) (ZINC CATION	- UNII:13S1S8SF	37) ZINC GLU	CONATE	.0165 g in 1 ml	
Ingredient Name       Strength         WATER (UNII: 059QF0K00R)         TAURINE (UNII: 1EQV5MLY3D)         METHYLPARABEN (UNII: A218C7H19T)         PROPYLPARABEN (UNII: 281X2SC10H)         FD&C BLUE NO. 1 (UNII: H3R47K3TBD)         CARBOXYMETHYLCELULOSE (UNII: 05JZ17B19X)         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       1       1       1         S								
WATER (UNII: 059QF0K00R)       Image: Constraint of the second seco	Inactive Ingredie	ents						
TAURINE (UNII: 1EQV5MLY3D)       Image: constraint of the state of th			Strength					
METHYLPARABEN (UNII: 2/81/25C10H)       Image: constraint of the state of the stat	WATER (UNII: 059QF0K	00R)						
PROPYLPARABEN (UNII: 28IX2SC10H)       Image: Construct of the second seco	TAURINE (UNII: 1EQV5N	(LY3D)						
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)         CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       Image: Colspan="2">Image: Colspan="2" Image: Colspan="2	METHYLPARABEN (UN	II: A2I8C7HI9	T)					
Arketing Information         Marketing Start Date         Marketing Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       Image: Comparison of the start Date       Marketing End Date         1       S9 mL in 1 BOTTLE       Image: Comparison of the start Date       Marketing End Date         Marketing Code of the start Date         Image: Comparison of the start Date       Marketing End Date         Marketing Code of the start Date         Image: Code of the start Date       Marketing Start Date         Image: Code of the start Date       Marketing Start Date         Image: Code of the start Date       Marketing Start Date         Image: Unapproved drug       01/01/2001	PROPYLPARABEN (UNI	I: Z8IX2SC1	OH)					
Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       1	FD&C BLUE NO. 1 (UN	III: H3R47K31	FBD)					
Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       Image: Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       Image: Start Date       Marketing End Date         1       S9 mL in 1 BOTTLE       S9 mL in 1 BOTTLE       Image: Start Date       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date         unapproved drug       01/01/2001       Image: Start Date       Image: Start Date       Image: Start Date	CARBOXYMETHYLCEL	LULOSE (UI	NII: 05JZ17B19X)					
#       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:86045-3300-1       12 in 1 BOX       1       1       1         59 mL in 1 BOTTLE       59 mL in 1 BOTTLE       1       1       1         Marketing Information         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date         unapproved drug       01/01/2001       01/01/2001       1       1       1								
1       NDC:86045-3300-1       12 in 1 BOX         1       59 mL in 1 BOTTLE         Marketing Information         Marketing Category         unapproved drug       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date	Packaging							
1       59 mL in 1 BOTTLE         Marketing Information         Marketing Category       Application Number or Monograph Citation         unapproved drug       01/01/2001	# Item Code	Packag	e Description	Marketing	Start Date	Marketi	ng End Date	
Marketing Information         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date         unapproved drug       01/01/2001       01/01/2001	<b>1</b> NDC:86045-3300-1	12 in 1 BO	Х					
Marketing Category     Application Number or Monograph Citation     Marketing Start Date     Marketing End Date       unapproved drug     01/01/2001	1	59 mL in 1	BOTTLE					
Marketing Category     Application Number or Monograph Citation     Marketing Start Date     Marketing End Date       unapproved drug     01/01/2001								
Marketing Category     Application Number or Monograph Citation     Marketing Start Date     Marketing End Date       unapproved drug     01/01/2001	Marketing Inf	formati	on					
unapproved drug	Marketing		ion Number or M	onograph		Start M		
	unapproved drug						2410	

Labeler - Addison Biological Laboratory, Inc. (118396730)

Registrant - Addison Biological Laboratory, Inc. (118396730)

Establishment								
Name	Address	ID/FEI	<b>Business Operations</b>					
Addison Biological Laboratory, Inc.		118396730	manufacture					
Establishment								

Name	Address	ID/FEI	<b>Business Operations</b>
Jost Chemical Co.		147882294	api manufacture

Revised: 11/2023