# COLD-EEZE- zinc gluconate lozenge ProPhase Labs, Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

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Cold-EEZE<sup>®</sup> Zinc Gluconate Glycine Cold Remedy

**Drug Facts** 

#### Active ingredient (per lozenge)

Zincum Gluconicum 2x (13.3mg)

#### **Purpose**

Cold Remedy

#### Uses

- to reduce the duration of the common cold
- reduces the severity of cold symptoms: cough, sore throat, stuffy nose, sneezing, post nasal drip and/or hoarseness

#### **Warnings**

#### Ask a doctor before use if you

• are taking minocycline, doxycycline, tetracycline or are on coumadin therapy, zinc treatment may inhibit the absorption of these medicines

**Stop use and ask your healthcare practitioner** if symptoms persist beyond 7 days.

 ${\sf COLD\text{-}EEZE}^{\circledR}$  Lozenges are formulated to reduce the duration of common cold symptoms and may be insufficient treatment for Influenza or Allergies.

**If pregnant or breast-feeding,** ask a health professional before use.

Keep out of reach of children.

#### **Directions**

- adults and children 12 years and over
- for best results, begin treatment at start of symptoms (within 24-48 hours of onset)
- repeat every 2 4 hours as needed until all symptoms subside
- completely dissolve a COLD-EEZE® lozenge in mouth (do not chew)
- recommended daily dosage is 6 lozenges for adults and 4 lozenges for ages 12-17
- children under 12 years of age should consult a health professional prior to use

#### Other information

- avoid minor stomach upset Do not dissolve COLD-EEZE® lozenges on an empty stomach
- avoid citrus fruits or juices and products containing citric acid 1/2 hour before or after taking COLD-EEZE® lozenges as they may diminish product effectiveness, otherwise, drink plenty of

#### fluids

- store in a cool dry place after opening
- gluten-free

#### **Inactive ingredients**

corn syrup, glycine, natural flavors and sucrose. No artificial colors or preservatives.

#### **Questions or Comments**

Call 1-800-505-COLD (9AM-5PM EST)

#### PRINCIPAL DISPLAY PANEL - 18 Cherry Lozenge Carton

GREAT NEW TASTE

**Cold-EEZE**®

Zinc Gluconate Glycine

#### COLD REMEDY

- Clinically proven to reduce the duration of the common cold ®
- + #1 Pharmacist Recommended
- + Shortens your cold, works fast

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Drunu:

**Pharmacy** 

**Times** 

18 Cold Remedy Lozenges

Homeopathic

All Natural Cherry Flavor

with other natural flavors



Clinically proven to reduce the duration of the common cold®

18 Cold Remedy Lozenges

Zinc Gluconate Glycine

GREAT NEW TASTE



# **COLD REMEDY**

- Clinically proven to reduce the duration of the common cold ®
- # #1 Pharmacist Recommended
- Shortens your cold, works fast
- 18 Cold Remedy Lozenges

Homeopathic



All Natural Cherry Flavor with other natural flavors



+ #1 Pharmacist Recommended

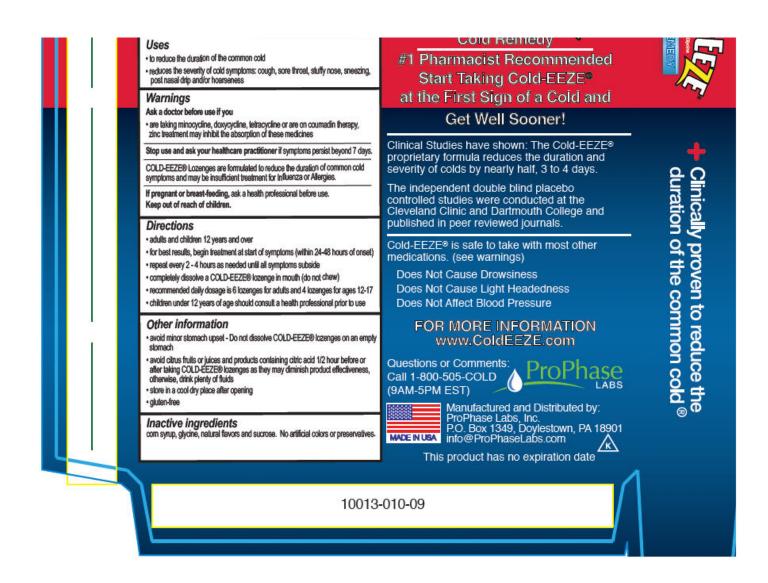
🕇 Shortens your cold, works fast

**Drug Facts** 

Active ingredient (per lozenge) Zincum Gluconicum 2x (13.3mg)..... Purpose .....Cold Remedy







#### PRINCIPAL DISPLAY PANEL - 24 Cherry Lozenge Carton

GREAT NEW TASTE

Cold-EEZE®

Zinc Gluconate Glycine

33%

**MORE** 

**FREE** 

#### **COLD REMEDY**

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24 Cold Remedy Lozenges

Homeopathic

**All Natural Cherry Flavor**with other natural flavors



Clinically proven to reduce the duration of the common cold®

24 Cold Remedy Lozenges

# GREAT NEW TASTE Zinc Gluconate Glycine





# COLD REMEDY

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- + Shortens your cold, works fast





Homeopathic



**All Natural Cherry Flavor** with other natural flavors





#1 Pharmacist Recommended

Shortens your cold, works fast

**Drug Facts** 

Active ingredient (per lozenge)







#### PRINCIPAL DISPLAY PANEL - 18 Tropical Orange Lozenge Carton

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Cold-EEZE®

Zinc Gluconate Glycine

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18 Cold Remedy

# Lozenges

Homeopathic

All Natural Tropical Orange Flavor with other natural flavors



Clinically proven to reduce the duration of the common cold®

18 Cold Remedy Lozenges



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# **COLD REMEDY**

- Clinically proven to reduce the duration of the common cold®
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- Shortens your cold, works fast



Homeopathic



All Natural Tropical Orange Flavor with other natural flavors



👆 Shortens your cold, works fast #1 Pharmacist Recommended

COLD REMED

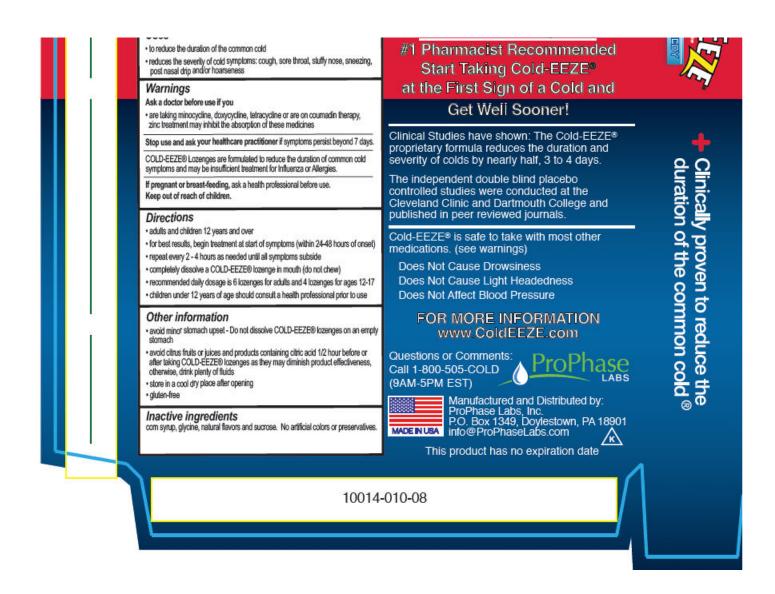
#### **Drug Facts**

Active ingredient (per lozenge) Purpose Zincum Gluconicum 2x (13.3mg)... Cold Remedy

Uses







#### PRINCIPAL DISPLAY PANEL - 24 Tropical Orange Lozenge Carton

GREAT NEW TASTE

Cold-EEZE®

Zinc Gluconate Glycine

33%

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#### COLD REMEDY

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Lozenges

Homeopathic

All Natural
Tropical Orange Flavor
with other natural flavors



Clinically proven to reduce the duration of the common cold®

24 Cold Remedy Lozenges

GREAT NEW TASTE







# **COLD REMEDY**

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- #1 Pharmacist Recommended
- Shortens your cold, works fast





Homeopathic

All Natural









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#### PRINCIPAL DISPLAY PANEL - 18 Lemon Lime Lozenge Carton

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**Cold-EEZE**<sup>®</sup> *Zinc Gluconate Glycine* 

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- + #1 Pharmacist Recommended
- + Shortens your cold, works fast

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18 Cold Remedy

# Lozenges

Homeopathic

**All Natural Lemon Lime Flavor**with other natural flavors



Clinically proven to reduce the duration of the common cold ®

18 Cold Remedy Lozenges





# COLD REMEDY

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- + Shortens your cold, works fast
- Cold Remedy Lozenges

Homeopathic





All Natural **Lemon Lime Flavor** with other natural flavors



🕇 #1 Pharmacist Recommended

Shortens your cold, works fast

**Drug Facts** 

Active ingredient (per lozenge) Zincum Gluconicum 2x (13.3mg)...

Purpose







#### PRINCIPAL DISPLAY PANEL - 24 Lemon Lime Lozenge Carton

GREAT NEW TASTE

Cold-EEZE®

Zinc Gluconate Glycine

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#### COLD REMEDY

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24 Cold Remedy Lozenges

Homeopathic

**All Natural Lemon Lime Flavor**with other natural flavors



Clinically proven to reduce the duration of the common cold®

24 Cold Remedy Lozenges

# GREAT NEW TASTE Zinc Gluconate Glycine





# COLD REMEDY



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- #1 Pharmacist Recommended
- Shortens your cold, works fast

Cold Remedy Lozenges





Lemon Lime Flavor with other natural flavors





COLD REMEDY

**Drug Facts** 

Active ingredient (per lozenge)





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#### PRINCIPAL DISPLAY PANEL - 18 Strawberries & Cream Lozenge Carton

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**Cold-EEZE**<sup>®</sup> Zinc Gluconate Glycine

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- Shortens your cold, works fast

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Homeopathic

**All Natural Strawberries & Cream Flavor** with other natural flavors



Clinically proven to reduce the duration of the common cold ®

18 Cold Remedy Lozenges





# **COLD REMEDY**

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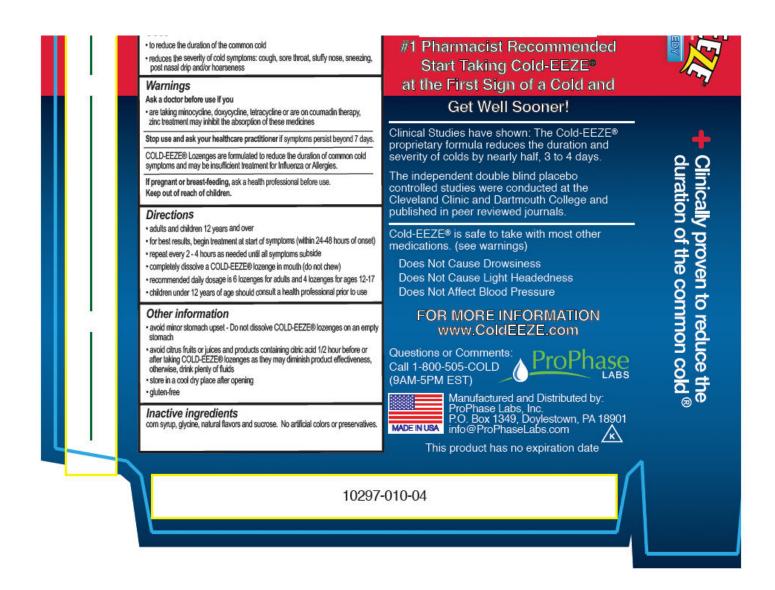
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 Shortens your cold, works fast

**Drug Facts** 

Uses







#### PRINCIPAL DISPLAY PANEL - 24 Strawberries & Cream Lozenge Carton

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**All Natural Strawberries** & Cream Flavor with other natural flavors



Clinically proven to reduce the duration of the common cold®

24 Cold Remedy Lozenges

# GREAT NEW TASTE Zinc Gluconate Glycine





# COLD REMEDY



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- #1 Pharmacist Recommended
- Shortens your cold, works fast



Homeopathic



All Natural Strawberries & Cream Flavor with other natural flavors











Shortens your cold, works fast #1 Pharmacist Recommended

**Drug Facts** 

Active ingredient (per lozenge) Zincum Gluconicum 2x (13.3mg).

Purpose







#### PRINCIPAL DISPLAY PANEL - 18 Mint Frost Lozenge Carton

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Cold-EEZE®

Zinc Gluconate Glycine

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- + Shortens your cold, works fast

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# Lozenges

Homeopathic

**All Natural Mint Frost Flavor**with other natural flavors



Clinically proven to reduce the duration of the common cold ®

18 Cold Remedy Lozenges





# **COLD REMEDY**

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- + Shortens your cold, works fast



Cold Remedy Lozenges

Homeopathic



All Natural Mint Frost Flavor with other natural flavors



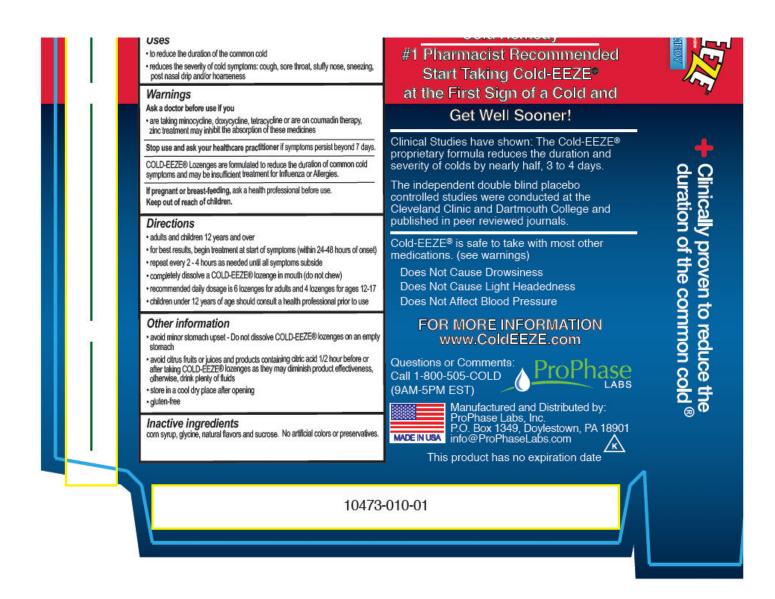
#1 Pharmacist Recommended

Shortens your cold, works fast

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Drug Facts

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#### PRINCIPAL DISPLAY PANEL - 24 Mint Frost Lozenge Carton

GREAT NEW TASTE

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Zinc Gluconate Glycine

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All Natural
Mint Frost Flavor
with other natural flavors



Clinically proven to reduce the duration of the common cold®

24 Cold Remedy Lozenges

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# Zinc Gluconate Glycine





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- Shortens your cold, works fast



Cold Remedy Lozenges



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Drug Facts





#### COLD-EEZE

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0011
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]	

Inactive Ingredients		
Ingredient Name	Strength	
Corn Syrup (UNII: 9G5L16BK6N)		
Glycine (UNII: TE7660XO1C)		
Sucrose (UNII: C151H8 M554)		

Product Characteristics				
Color	WHITE (Semi-Translucent)	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	CHERRY	Imprint Code	P	
Contains				

Pac	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NI	DC:61941-0011-1	24 in 1 CASE		
1 NI	DC:61941-0011-8	18 in 1 PACKAGE		
2 NI	DC:61941-0011-2	48 in 1 CASE		
2 NI	DC:61941-0011-8	18 in 1 PACKAGE		
3 NI	DC:61941-0011-3	144 in 1 CASE		
3 NI	DC:61941-0011-8	18 in 1 PACKAGE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
UNAPPROVED HOMEOPATHIC		06/07/1994		

# **COLD-EEZE**

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0012
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]	

Inactive Ingredients		
Ingredient Name	Strength	
Corn Syrup (UNII: 9G5L16BK6N)		
Glycine (UNII: TE7660XO1C)		
Sucrose (UNII: C151H8M554)		

Product Characteristics			
Color	WHITE (Semi-Translucent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	CHERRY	Imprint Code	P

#### Contains

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:61941-0012-4	24 in 1 PACKAGE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
UNAPPROVED HOMEOPATHIC		06/07/1994		

# **COLD-EEZE**

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0031	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]

Inactive Ingredients		
Ingredient Name	Strength	
Corn Syrup (UNII: 9G5L16BK6N)		
Glycine (UNII: TE7660XO1C)		
Sucrose (UNII: C151H8M554)		

Product Characteristics				
Color WHITE (Semi-Translucent)		Score	no score	
Shape	OVAL	Size	23mm	
Flavor	TROPICAL FRUIT PUNCH (Tropical Orange)	Imprint Code	P	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-0031-1	24 in 1 CASE		
1	NDC:61941-0031-8	18 in 1 PACKAGE		
2	NDC:61941-0031-2	48 in 1 CASE		
2	NDC:61941-0031-8	18 in 1 PACKAGE		

3 NDC:61941-0031-3	144 in 1 CASE	
3 NDC:61941-0031-8	18 in 1 PACKAGE	ı

<b>Marketing Informat</b>	ion			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	e Marketing End Date	
UNAPPROVED HOMEOPATHIC		02/01/2003		

#### **COLD-EEZE**

zinc gluconate lozenge

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:61941-0032

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

 Ingredient Name
 Basis of Strength
 Strength

 Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)
 Zinc Gluconate
 2 [hp\_X]

# Inactive Ingredients Ingredient Name Strength Corn Syrup (UNII: 9G5L16BK6N) Glycine (UNII: TE7660 XO1C) Sucrose (UNII: C151H8 M554)

Product Characteristics			
Color WHITE (Semi-Translucent)		Score	no score
Shape	OVAL	Size	23mm
Flavor	TROPICAL FRUIT PUNCH (Tropical Orange)	Imprint Code	P
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-0032-4	24 in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	<b>Marketing Start Date</b>	Marketing End Date
UNAPPROVED HOMEOPATHIC		02/01/2003	

#### **COLD-EEZE**

zinc gluconate lozenge

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61941-0041

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

ı	9	<u> </u>		
l		Ingredient Name	Basis of Strength	Strength
l	Zinc Gluconate (UNII: U6	WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]

#### **Inactive Ingredients**

indexive ingredients	
Ingredient Name	Strength
Corn Syrup (UNII: 9G5L16BK6N)	
Glycine (UNII: TE7660 XO1C)	
Sucrose (UNII: C151H8 M554)	

#### **Product Characteristics**

Color	WHITE (Semi-Translucent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	LIME (Lemon Lime / Citrus)	Imprint Code	P
Contains			

#### **Packaging**

	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-0041-1	24 in 1 CASE		
1	NDC:61941-0041-8	18 in 1 PACKAGE		
2	NDC:61941-0041-2	48 in 1 CASE		
2	NDC:61941-0041-8	18 in 1 PACKAGE		
3	NDC:61941-0041-3	144 in 1 CASE		
3	NDC:61941-0041-8	18 in 1 PACKAGE		

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		02/01/2003	

#### **COLD-EEZE**

zinc gluconate lozenge

#### **Product Information**

	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0042
ı	Route of Administration	ORAL		

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]

Inactive Ingredients	
Ingredient Name	Strength
Corn Syrup (UNII: 9G5L16BK6N)	
Glycine (UNII: TE7660XO1C)	
Sucrose (UNII: C151H8M554)	

Product Characteristics				
Color	WHITE (Semi-Translucent)	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	LIME (Lemon Lime / Citrus)	Imprint Code	P	
Contains				

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 1	NDC:61941-0042-4	24 in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		02/01/2003	

# **COLD-EEZE**

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0051	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]

Inactive Ingredients				
Ingredient Name	Strength			
Corn Syrup (UNII: 9G5L16BK6N)				
Glycine (UNII: TE7660XO1C)				
Sucrose (UNII: C151H8 M554)				

Product Characteristics				
Color	WHITE (Semi-Translucent)	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	STRAWBERRY (Strawberry & Cream)	Imprint Code	P	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61941-0051-1	24 in 1 CASE			
1	NDC:61941-0051-8	18 in 1 PACKAGE			
2	NDC:61941-0051-2	48 in 1 CASE			
2	NDC:61941-0051-8	18 in 1 PACKAGE			
3	NDC:61941-0051-3	144 in 1 CASE			
3	NDC:61941-0051-8	18 in 1 PACKAGE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
UNAPPROVED HOMEOPATHIC		02/01/2003		

# **COLD-EEZE**

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0052	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]		

Inactive Ingredients				
Ingredient Name	Strength			
Corn Syrup (UNII: 9G5L16BK6N)				
Glycine (UNII: TE7660 XO1C)				

Sucrose (UNII: C151H8M554)

Product Characteristics				
Color	WHITE (Semi-Translucent)	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	STRAWBERRY (Strawberry & Cream)	Imprint Code	P	
Contains				

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61941-0052-4	24 in 1 PACKAGE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		02/01/2003	

# **COLD-EEZE**

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0071	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]	

Inactive Ingredients	
Ingredient Name	Strength
Corn Syrup (UNII: 9G5L16BK6N)	
Glycine (UNII: TE7660XO1C)	
Sucrose (UNII: C151H8M554)	

Product Characteristics				
Color	WHITE (Semi-Translucent)	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	MINT (Mint Frost)	Imprint Code	P	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61941-0071-1	24 in 1 CASE			
1	NDC:61941-0071-8	18 in 1 PACKAGE			
2	NDC:61941-0071-2	48 in 1 CASE			
2	NDC:61941-0071-8	18 in 1 PACKAGE			
3	NDC:61941-0071-3	144 in 1 CASE			
3	NDC:61941-0071-8	18 in 1 PACKAGE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		02/01/2010	

# **COLD-EEZE**

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0072	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Gluconate	2 [hp_X]	

Inactive Ingredients			
Ingredient Name	Strength		
Corn Syrup (UNII: 9G5L16BK6N)			
Glycine (UNII: TE7660XO1C)			
Sucrose (UNII: C151H8M554)			

Product Characteristics			
Color	WHITE (Semi-Translucent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	MINT (Mint Frost)	Imprint Code	P
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NI	DC:61941-0072-4	24 in 1 PACKAGE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	<b>Marketing Start Date</b>	Marketing End Date	
UNAPPROVED HOMEOPATHIC		02/01/2010		

# Labeler - ProPhase Labs, Inc. (620557298)

Establishment				
Name	Address	ID/FEI	Business Operations	
ProPhase Labs, Inc.		620557298	LABEL, ANALYSIS	

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharmaloz Manufacturing, Inc.		067101998	MANUFACTURE, ANALYSIS, PACK, REPACK	

Revised: 3/2011 ProPhase Labs, Inc.