### COLD-EEZE- zinc gluconate lozenge Mylan Consumer Healthcare, 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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#### **Drug Facts**

### Active ingredient (per lozenge)

Zincum Gluconicum 2x (13.3 mg Zinc)

#### Purpose

Cold Remedy

# Uses

- to reduce the duration of the common cold
- reduces the severity of cold symptoms: cough, sore throat, nasal congestion, 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.

Cold-EEZE<sup>®</sup> lozenges are formulated to reduce the duration of the common cold and its symptoms and is insufficient treatment for Influenza or Allergies.

**Diabetic Warning:** sugar replacements may affect blood sugar levels.

# If pregnant or breastfeeding,

ask a healthcare practitioner before use.

# Keep out of reach of children.

# Directions

Adults and children 12 years and over:

- take Cold-EEZE<sup>®</sup> when you have cold symptoms
- completely dissolve a Cold-EEZE<sup>®</sup> lozenge in mouth (do not chew)
- repeat every 2-4 hours as needed until all symptoms subside
- recommended daily dosage is 6 lozenges for adults and 4 lozenges for ages 12-17

Children under 12 years of age should consult a healthcare practitioner prior to use

### Other information

- do not take Cold-EEZE<sup>®</sup> lozenges on an empty stomach to avoid possible minor stomach upset
- do not eat or drink for 15 minutes after use
- store in a cool, dry place after opening; best if used within 6 months after opening
- gluten free
- product may produce a laxative effect

# **Inactive ingredients**

Acesulfame-K, glycine, Isomalt, natural flavors. No artificial colors or preservatives.

Clinical Studies have shown: The unique Cold- $\text{EEZE}^{\textcircled{R}}$  formula reduces the duration of the common cold by almost half.

The double blind placebo controlled studies were conducted at the Cleveland Clinic and Dartmouth College and published in peer reviewed journals.

Cold-EEZE<sup>®</sup> is safe to take with most other medications and is gluten free. (see warnings)

Does Not Cause Drowsiness

Does Not Cause Light Headedness

Does Not Affect Blood Pressure

# For cold-fighting tips and more about the Cold-EEZE $^{\ensuremath{\mathbb{R}}}$ science, go to www.ColdEEZE.com

# **Questions or Comments:**

Call 1-800-505-2653 (M-F: 8AM-5PM ET)

\*Based on unit sales of cold shortening, homeopathic zinc lozenges

<sup>+</sup>THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

This product has no expiration date.

Manufactured for: **Mylan Consumer Healthcare, Inc.** Morgantown, WV 26505 U.S.A.

# Principal Display Panel – Sugar Free Cherry Lozenges

NDC 46017-324-83

The Original and #1 Best Selling Zinc Lozenges\*

Cold-EEZE<sup>®</sup> ZINC GLUCONATE GLYCINE SHORTENS YOUR COLD WORKS FASTER<sup>®+</sup>

SUGAR FREE

CLINICALLY PROVEN to reduce the duration of the common cold<sup>®+</sup>

**#1 PHARMACIST RECOMMENDED** 

18 LOZENGES HOMEOPATHIC

RESEALABLE BAG INSIDE

NATURAL FLAVOR Sugar Free Wild Cherry

- + Take Cold-EEZE<sup>®</sup> when you have a cold<sup>+</sup>
- + Continue until symptoms are gone\*
- + Gluten Free
- <sup>+</sup> Our clinically proven formula releases zinc ions in the mouth that shorten the duration of the common cold<sup>+</sup>





# Principal Display Panel – Sugar Free Honey Lemon

NDC 46017-334-83

The Original and #1 Best Selling Zinc Lozenges\*

Cold-EEZE<sup>®</sup> ZINC GLUCONATE GLYCINE

SHORTENS YOUR COLD WORKS FASTER<sup>®+</sup>

# SUGAR FREE

CLINICALLY PROVEN to reduce the duration of the common cold<sup>®+</sup>

# **#1 PHARMACIST RECOMMENDED**

18 LOZENGES HOMEOPATHIC

RESEALABLE BAG INSIDE

NATURAL FLAVOR Sugar Free Honey Lemon

- + Take Cold-EEZE<sup>®</sup> when you have a cold<sup>+</sup>
- + Continue until symptoms are gone\*
- + Gluten Free
- <sup>+</sup> Our clinically proven formula releases zinc ions in the mouth that shorten the duration of the common cold<sup>+</sup>





Principal Display Panel – Sugar Free Pomegranate

NDC 46017-335-83

The Original and #1 Best Selling Zinc Lozenges\*

Cold-EEZE<sup>®</sup> ZINC GLUCONATE GLYCINE

SHORTENS YOUR COLD WORKS FASTER<sup>®+</sup>

**SUGAR FREE** 

CLINICALLY PROVEN to reduce the duration of the common cold<sup>®+</sup>

**#1 PHARMACIST RECOMMENDED** 

18 LOZENGES HOMEOPATHIC

**RESEALABLE BAG INSIDE** 

NATURAL FLAVOR Sugar Free Pomegranate

- + Take Cold-EEZE<sup>®</sup> when you have a cold<sup>+</sup>
- + Continue until symptoms are gone\*
- + Gluten Free
- <sup>+</sup> Our clinically proven formula releases zinc ions in the mouth that shorten the duration of the common cold<sup>+</sup>





zinc gluconate lozenge					
<b>Product Information</b>					
Product Type	HUMAN OTC DRUG	Item Code (Sour	ce)	NDC:4601	17-324
Route of Administration	ORAL				
Active Ingredient/Active					
	Ingredient Name		Basis of St	rength	Strengtl
Zinc Gluconate (UNII: U6WSN55	Q1Z) (ZINC CATION - UNII:13S1S	88SF37)	Zinc Gluconate		2 [hp_X]
Inactive Ingredients					
	Ingredient Name			St	rength
ACESULFAME POTASSIUM (UN	NII: 230V73Q5G9)				
GLYCINE (UNII: TE7660XO1C)					

Color	WHITE (semi-translucent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	CHERRY	Imprint Code	Р
Contains			
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:46017-324-83	1 in 1 BOX	10/11/2018	
1	18 in 1 BAG; Type 0: Not a Combination Product		
2 NDC:46017-324-84	18 in 1 BAG; Type 0: Not a Combination Product	09/28/2018	
	1 in 1 BOX	10/12/2018	
<b>3</b> NDC:46017-324-44	24 in 1 BAG; Type 0: Not a Combination Product		
3 NDC:46017-324-44 3			

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		09/28/2018	

# COLD-EEZE

zinc gluconate lozenge

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46017-334		
Route of Administration	ORAL				

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
Zinc Gluconate (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	Zinc Gluconate	2 [hp_X]

# Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
GLYCINE (UNII: TE7660XO1C)	
ISOMALT (UNII: S870P5502W)	

Product Characteristics					
Color	WHITE (semi-translucent)	Score	no score		
Shape	OVAL	Size	23mm		
Flavor	HONEY (honey lemon)	Imprint Code	Р		
Contains					

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46017-334-83	1 in 1 BOX	09/28/2028	
1		18 in 1 BAG; Type 0: Not a Combination Product		
N	/Iarketing Info	ormation		
	Marketing Categor	y Application Number or Monograph Citation	on Marketing Start Date	Marketing End Date
U	napproved homeopath	ic	09/28/2018	

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C	OLD-EEZE							
zi	nc gluconate lozer	ige						
F	Product Informa	tion						
P	Product Type     HUMAN OTC DRUG     Item Code (Source)				NDC:46017-335			
F	Route of Administra	tion	ORAL					
A	ctive Ingredien							
			redient Name			Basis of S	-	Strength
Z	inc Gluconate (UNII:	U6WSN5SQ1Z)	(ZINC CATION - UNII:13S1S8SF	37)		Zinc Gluconate	2	2 [hp_X]
T	nactiva Ingradia	nto						
1	Inactive Ingredients Ingredient Name Strength							
Δ	ACESULFAME POTASSIUM (UNII: 230V73Q5G9)							
	Glycine (UNII: TE7660X01C)							
	<b>ISOMALT</b> (UNII: \$870P5502W)							
_								
P	roduct Characte	eristics						
С	olor	WHITE (semi-tra	anslucent)		Score		no s	core
S	hape	OVAL			Size		23m	m
F	lavor	POMEGRANAT	E		Imprint Coo	le	Р	
C	ontains							
-	1.							
	ackaging	_						- 1
#			Package Description		Marketing	Start Date	Marketi	ng End Date
	NDC:46017-335-83	1 in 1 BOX	une O. Not a Combination Deadler		09/28/2028			
1		10 III 1 BAG; I	ype 0: Not a Combination Produc	.t				

Marketing Information					
plication Number or Monograph Citation	Marketing Start Date	Marketing End Date			
	09/28/2018				
	plication Number or Monograph Citation				

Labeler - Mylan Consumer Healthcare, Inc. (831410522)

Revised: 12/2017

Mylan Consumer Healthcare, Inc.