

COLD-EEZE PLUS DEFENSE- zinc gluconate, sambucus nigra flower, rosa canina leaf, echinacea purpurea, and avena sativa leaf 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.

Drug Facts

Active Ingredient (per lozenge)

Zinc Gluconate 1X HPUS† (2.22%) (13.3 mg zinc)

Sambucus Nigra 1X HPUS† (1.11%)

Avena Sativa L. 2X HPUS† (0.02%)

Rosa Canina (Rose Hips) 2X HPUS† (0.09%)

Echinacea Purpurea 3X HPUS† (0.04%)

†The letters 'HPUS' indicates that the active ingredient is in the official Homeopathic Pharmacopeia of the United States.

Purpose

Cold Remedy

Promotes immune support*

Helps with general debility and fatigue*

Uses

- reduces the duration of the common cold
- reduces the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip and/or hoarseness
- supports immune system health*
- helps with a general debility and fatigue*

Warnings

Do not use for treatment of influenza or allergies. This product is intended only to reduce the duration of the common cold and its symptoms.

Ask a doctor before use if you have

- diabetes
- multiple sclerosis (MS)
- rheumatoid arthritis (RA) or other auto-immune condition

Ask a doctor or pharmacist before use if you are

taking minocycline, doxycycline, tetracycline or are on Coumadin (warfarin) therapy. Zinc treatment may inhibit the absorption of these medicines.

When using this product

do not take on an empty stomach (to avoid possible minor stomach upset).

Stop use and ask your healthcare practitioner if

symptoms persist beyond 7 days.

If pregnant or breast feeding,

ask a healthcare professional before use.

Keep out of reach of children.**Directions**

- take one at the onset of symptoms
- do not swallow whole
- dissolve entire lozenge in mouth
- do not eat or drink for 15 minutes after use
- do not chew
- repeat every 2-4 hours until symptoms subside

Adults 18 years and over	do not exceed 6 lozenges per day
Children 12 to under 18 years	do not exceed 4 lozenges per day
Children under 12 years	ask a doctor before use

Other information

- store in a cool, dry place after opening
- best if used within 6 months after opening

Inactive ingredients

Corn syrup, glycine, natural colors, natural flavors and sucrose.

Questions or comments?

Call **1-800-505-2653** (Monday-Friday: 8am-5pm EST)

This product has not been evaluated by the FDA.

***Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.**

No artificial colors or preservatives

Manufactured for:

Mylan Consumer Healthcare, Inc.

Morgantown, WV 26505 U.S.A.

This product has no expiration date

Principal Display Panel – Citrus with Elderberry

NDC 46017-323-96

Cold-EEZE®

HOMEOPATHIC

SHORTENS YOUR COLD

Plus DEFENSE

- ☐ **Promotes Immune Health***
- ☐ **Helps with Fatigue***

12 LOZENGES

HOMEOPATHIC

RESEALABLE BAG INSIDE

NATURAL FLAVOR

Citrus with Elderberry

- + Shortens your cold
- + Promotes Immune Health*
- + Helps with Fatigue*
- + Releases zinc ions in the mouth®
- + #1 pharmacist recommended zinc lozenge brand

Citrus with Elderberry 400104004

No artificial colors or preservatives

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

This product has not been evaluated by the FDA.

Call for more information
Call 1-800-665-4669 (Monday-Friday, 9am-5pm EST)

Ingredients
Citrus, elderberry, natural colors, natural flavors and sucrose

Other information
Store in a cool, dry place after opening. Best if used within 6 months after opening.

Children under 12 years	do not exceed 4 lozenges per day
Children 12 to under 18 years	do not exceed 6 lozenges per day
Adults 18 years and over	do not exceed 6 lozenges per day

do not chew
do not eat or drink for 15 minutes after use
repeat every 2-4 hours until symptoms subside

Directions
Do not swallow whole
Take one at the onset of symptoms
Place one in mouth
Do not eat or drink for 15 minutes after use
Repeat every 2-4 hours until symptoms subside

Warnings
Do not use for treatment of influenza or allergies. This product is intended only to reduce the duration of the common cold and its symptoms.
Ask a doctor before use if you have:
diabetes
multiple sclerosis (MS)
rheumatoid arthritis (RA) or other auto-immune condition

Uses
Reduces the duration of the common cold
Reduces the severity of cold symptoms: cough, sore throat, nasal congestion, post nasal drip
and/or hoarseness
Supports immune system health
Helps with general debility and fatigue

Drug Facts
Active ingredient (per lozenge):
Zinc Gluconate 1X HPUS (12.22%) (13.3 mg zinc)
Cold Remedy
Promotes immune support
Helps with general debility and fatigue
Avena Sativa L. 2X HPUS (0.02%)
Sambucus Nigra 1X HPUS (1.11%)
Promotes immune support

Other information
When using this product do not take on an empty stomach (to avoid possible minor stomach upset).
Stop use and ask your healthcare practitioner if symptoms persist beyond 7 days.
If pregnant or breast feeding, ask a healthcare professional before use.
Keep out of reach of children.

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Cold-EEZE
HOMEOPATHIC
12 LOZENGES
Citrus with Elderberry

SHORTENS YOUR COLD Plus DEFENSE

The Original and #1 Best Selling Zinc Lozenges*

Cold-EEZE
HOMEOPATHIC

SHORTENS YOUR COLD Plus DEFENSE

- ☐ Promotes Immune Health*
- ☐ Helps with Fatigue*



12 LOZENGES

Cold-EEZE
HOMEOPATHIC
NDC 4001 7-323-96

Cold-EEZE
HOMEOPATHIC
NDC 4001 7-323-96

Releases zinc ions in the mouth*
#1 pharmacist recommended zinc lozenge brand

Shortens your cold
Promotes Immune Health*
Helps with Fatigue*



COLD-EEZE PLUS DEFENSE

zinc gluconate, sambucus nigra flower, rosa canina leaf, echinacea purpurea, and avena sativa leaf lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46017-323
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Gluconate (UNII: U6WSN5SQ1Z) (Zinc Cation - UNII:13S1S8SF37)	Zinc Gluconate	1 [hp_X]
Sambucus Nigra Flower (UNII: 07V4DX094T) (Sambucus Nigra Flower - UNII:07V4DX094T)	Sambucus Nigra Flower	1 [hp_X]
ROSA CANINA LEAF (UNII: J3N2Z889QP) (ROSA CANINA LEAF - UNII:J3N2Z889QP)	ROSA CANINA LEAF	2 [hp_X]
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	3 [hp_X]
AVENA SATIVA LEAF (UNII: 206PI19V7R) (AVENA SATIVA LEAF - UNII:206PI19V7R)	AVENA SATIVA LEAF	2 [hp_X]

Inactive Ingredients

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

Product Characteristics

Color	PURPLE	Score	no score
Shape	OVAL	Size	23mm
Flavor	CITRUS (citrus with elderberry)	Imprint Code	P
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46017-323-96	1 in 1 BOX	08/28/2018	
1		12 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:46017-323-95	1 in 1 BOX	10/10/2018	
2		16 in 1 BAG; Type 0: Not a Combination Product		
3	NDC:46017-323-90	2 in 1 BAG; Type 0: Not a Combination Product	11/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		08/28/2018	

Labeler - Mylan Consumer Healthcare, Inc. (831410522)

Revised: 8/2019

Mylan Consumer Healthcare, Inc.