

FIRST AID DIRECT COLD-EEZE COLD REMEDY- zinc gluconate lozenge **Cintas Corporation**

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.

First Aid Direct Cold-EEZE Cold Remedy

Active ingredient (per lozenge)

Zinc Gluconate 2X HPUS† (2.3%) 13.3 mg zinc)

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

Purpose

Cold remedy

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

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 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 doctor if symptoms persist more than 7 days

If pregnant or breastfeeding, ask a healthcare professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take one lozenge at the onset of symptoms
- dissolve entire lozenge in mouth
- do not chew
- do not swallow whole
- do not eat or drink for 15 minutes after use
- 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 flavors, sucrose

Questions?

1-800-327-2704 m-F 8am-5pm EST

Principal Display Panel

Cold-EEZE®

Cold Remedy Lozenge

Zinc Gluconate Homeopathic

NATURAL CHERRY FLAVOR

Formulated to reduce the duration of the common cold when taken at the first sign of symptoms.

20 Lozenges per box

Cold-EEZE® is a registered trademark of Vespyr Brands®, Inc.

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FIRST AID DIRECT COLD-EEZE COLD REMEDY			
zinc gluconate lozenge			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961-105
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	2 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
GLYCINE (UNII: TE7660XO1C)	
SUCROSE (UNII: C151H8M554)	
CHERRY (UNII: BUC5I9595W)	

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:42961-105-02	20 in 1 PACKAGE	07/20/2023	
1	NDC:42961-105-01	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/20/2023	

Labeler - Cintas Corporation (056481716)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	manufacture(42961-105)

Revised: 7/2023

Cintas Corporation