COLD-EEZE PLUS NIGHTTIME MULTI-SYMPTOM RELIEF- zinc gluconate, eupatorium perfoliatum flowering top, sambucus nigra flower, valerian, chamomile, mentha piperita, myrrh, and glycyrrhiza glabra leaf tablet, orally disintegrating 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.

Cold-EEZE® Plus Nighttime Multi-Symptom Relief

Drug Facts

Active ingredient (per tablet)	Purpose
Zincum Gluconicum 1X	Cold Remedy
Eupatorium perfoliatum 1X	For temporary relief of flu
Eupatorium perromatum 1A	symptoms
Sambucus nigra 1X	(cough, nasal and chest congestion
Sambucus liigia 174	and irritated respiratory tract)
Valeriana Officinalis 1X	Sleep Disorder Remedy
Chamomile (Matricaria recutita) 2X	Relaxation and Calming
Mentha Piperita 2X	For temporary relief of cough
Myrrha 2X	For temporay relief of Sore Throat
Chromphiga C. I. (Licopica Doot) 2V	For temporary relief of Irritated
Glycyrrhiza G.L. (Licorice Root) 3X	Throat

Uses

- to reduce the duration of the common cold
- reduces the severity of cold and flu symptoms: cough, sore throat, nasal and chest congestion, post nasal drip and/or hoarseness
- helps for temporary relief of Sore Throat
- helps to relax and sleep easier to get rested

Warnings

Ask a doctor before use if you

- are taking fluvoxamine (Luvox), minocycline, doxycycline, tetracycline or are on Coumadin therapy, as zinc treatment may inhibit the absorption of these medicines
- are under medical supervision and/or are taking tranquilizers, sedatives or anti-seizure medicines
- are under medical supervision for diabetes or have multiple sclerosis (MS), rheumatoid arthritis (RA) or an auto-immune condition

Sore Throat Warning

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly.

Do not use

- if taking loperamide
- while operating a motor vehicle or machinery or consuming alcohol

Stop use and ask your healthcare practitioner if symptoms persist for more than 7 days or are accompanied by fever, rash or persistent headache

Cold-EEZE[®] Plus Nighttime Multi-Symptom Relief Cold & Flu QuickMelts[®] is a combination product formulated to help you to sleep easier, reduce the duration of the common cold and to help for temporary relief of cold and flu symptoms. It is insufficient treatment for Influenza or Allergies.

If pregnant or breastfeeding, ask a healthcare practitioner 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 Cold-EEZE® Plus Nighttime Multi-Symptom Relief Cold & Flu QuickMelts® at night when you have cold or flu symptoms
- Adults:
 - Dissolve entire tablet in mouth. Do not chew. Do not swallow whole.
 - Take 1 tablet 1 hour before bedtime
 - Do not eat or drink for 15 minutes after use, otherwise, drink plenty of fluids
- Recommended dose is 1 tablet for adults
- Allow 6-8 hours for sleep after taking tablet
- For individuals under the age of 18, consult a healthcare practitioner before use

Other information

- Do not take Cold-EEZE® Plus Nighttime Multi-Symptom Relief Cold & Flu QuickMelts® on an empty stomach to avoid possible minor stomach upset
- Store in a cool and dry place

Inactive ingredients

crospovidone, glycine, magnesium stearate, malic acid, maltodextrin, mannitol, microcrystalline cellulose, natural color from carrot and hibiscus concentrates, natural flavors, natural menthol flavor, polyethylene glycol, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, stevia, sucralose

Questions or Comments Call 1-800-505-2653 (M-F: 9AM-5PM EST)

Distributed by: ProPhase Labs, Inc. P.O. Box 1349, Doylestown PA 18901

PRINCIPAL DISPLAY PANEL - 18 Tablet Blister Pack Carton

Relax & <u>Sleep</u>!⁺ #1 Pharmacist Recommended

Cold-EEZE®

ZINC GLUCONATE GLYCINE

SHORTENS YOUR COLD, WORKS FASTER®+

Plus Nighttime

Multi-Symptom Relief Cold & Flu

ALSO HELPS RELIEVE:

- Oough+
- □ Sore Throat⁺
- ☐ Chest Congestion+

Fall as leep faster, naturally⁺

CLINICALLY PROVEN INGREDIENT

18
QuickMelts®
HOMEOPATHIC
(actual
size)

NATURAL FLAVOR Mixed Berry



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Drug Facts (continued)

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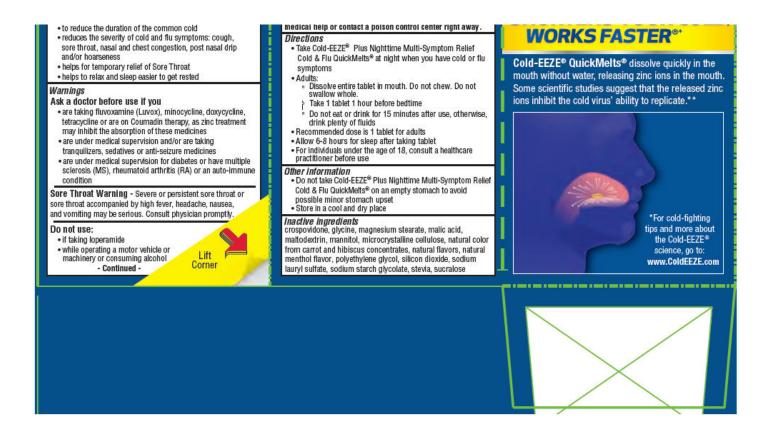
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Myrrha 2X .



COLD-EEZE PLUS NIGHTTIME MULTI-SYMPTOM RELIEF

zinc gluconate, eupatorium perfoliatum flowering top, sambucus nigra flower, valerian, chamomile, mentha piperita, myrrh, and glycyrrhiza glabra leaf tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0231
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]	
Eupatorium Perfoliatum Flowering Top (UNII: 1W0775VX6E) (Eupatorium Perfoliatum Flowering Top - UNII:1W0775VX6E)	Eupatorium Perfoliatum Flowering Top	1 [hp_X]	
Sambucus Nigra Flower (UNII: 07V4DX094T) (Sambucus Nigra Flower - UNII:07V4DX094T)	Sambucus Nigra Flower	1 [hp_X]	
Valerian (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)	Valerian	1 [hp_X]	
Chamomile (UNII: FGL3685T2X) (Chamomile - UNII:FGL3685T2X)	Chamomile	2 [hp_X]	
Mentha Piperita (UNII: 79M2M2UDA9) (Mentha Piperita - UNII:79M2M2UDA9)	Mentha Piperita	2 [hp_X]	
Myrrh (UNII: JC71GJ1F3L) (Myrrh - UNII:JC71GJ1F3L)	Myrrh	2 [hp_X]	
Glycyrrhiza Glabra Leaf (UNII: GH32M797Y9) (Glycyrrhiza Glabra Leaf - UNII:GH32M797Y9)	Glycyrrhiza Glabra Leaf	3 [hp_X]	

Inactive Ingredients	
Ingredient Name	Strength
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960 MK)	

GLYCINE (UNII: TE7660 XO 1C)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	GRAY	Score	no score
Shape	OCTAGON (8 SIDED)	Size	15mm
Flavor	BERRY (Mixed Berry)	Imprint Code	PM
Contains			

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
П	1 NDC:61941-0231-8	3 in 1 CARTON	08/15/2016	
	1	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		08/15/2016	

Labeler - ProPhase Labs, Inc. (620557298)

Establishment			
Name	Address	ID/FEI	Business Operations
Pro Phase Labs, Inc.		620557298	LABEL(61941-0231)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	PACK(61941-0231), ANALYSIS(61941-0231), REPACK(61941-0231), MANUFACTURE(61941-0231)

Revised: 7/2016 ProPhase Labs, Inc.