

COLD-EEZE DAYTIME AND NIGHTTIME QUICKMELTS- zinc gluconate, valerian, and chamomile

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®

Daytime/Nighttime QuickMelts®

Cold-EEZE® Daytime QuickMelts® (AM)

Drug Facts

Active ingredient (per tablet)

Zincum Gluconicum 1X

Purpose

Cold Remedy

Uses

Take 1 QuickMelt every 2-4 hours per Directions on inside panel.

- 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, as zinc treatment may inhibit the absorption of these medicines.

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

Cold-EEZE® QuickMelts® Daytime is formulated to reduce the duration of the common cold and its symptoms and is insufficient treatment for Influenza or Allergies.

If pregnant or breast feeding, ask a healthcare practitioner before use.

Keep out of reach of children.

Directions

- Take Cold-EEZE® Daytime QuickMelts® when you have cold symptoms
- Adults and Children 12 years and over:
 - Dissolve entire tablet in mouth. Do not chew.
Do not swallow whole.
 - Take 1 tablet at the onset of symptoms.
 - Repeat every 2-4 hours as needed until all symptoms subside.
 - Do not eat or drink for 15 minutes after use, otherwise, drink plenty of fluids.
 - Recommended daily dose is 6 tablets for adults and 4 tablets for ages 12-17 years.

- For children under 12 years of age, consult a healthcare practitioner before use.

Other information

- Do not take Cold-EEZE® QuickMelts® on an empty stomach to avoid possible minor stomach upset.
- Store in a cool and dry place.

Inactive ingredients

crospovidone, FD&C Red # 40, glycine, magnesium stearate, malic acid, mannitol, microcrystalline cellulose, natural mixed berry flavor, natural menthol flavor, polyethylene glycol, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, stevia, sucralose, talc.

Cold-EEZE® Nighttime QuickMelts® (PM)

Drug Facts

<i>Active ingredients (per tablet)</i>	<i>Purpose</i>
Zincum Gluconicum 1X	Cold Remedy
Valeriana Officinalis 1X	Sleep Disorder Remedy
Chamomile (<i>Matricaria recutita</i>) 2X	Relaxation and Calming

Uses

Take 1 Nighttime QuickMelt 1 hour before bedtime per Directions on inside panel.

- 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.
- helps to relax and sleep easier to get rested.

Warnings

Ask a doctor before using Cold-EEZE®

Nighttime QuickMelts® 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.
- do not take concomitantly with loperamide.

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

Cold-EEZE® Nighttime QuickMelts® is a combination product formulated to help you to sleep easier and to reduce the duration of the common cold and its symptoms and is insufficient treatment for Influenza or Allergies.

Do not take Cold-EEZE® Nighttime QuickMelts® while operating a motor vehicle or machinery or consuming alcohol.

Allow 6-8 hours for sleep after taking tablet.

If pregnant or breast feeding, ask a healthcare practitioner before use.

Keep out of reach of children.

Directions

- Take Cold-EEZE® Nighttime QuickMelts® at night when you have cold symptoms.
- Adults;
 - Dissolve entire tablet in mouth. Do not chew.
Do not swallow whole.
 - Take 1 Nighttime 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.
- For individuals under the age of 18, consult a healthcare practitioner before use.

Other information

- Do not take Cold-EEZE® QuickMelts® on an empty stomach to avoid possible minor stomach upset.
- Store in a cool and dry place.

Inactive ingredients

crospovidone, FD&C Blue #1 & #2, glycine, magnesium stearate, malic acid, **maltodextrin**, mannitol, microcrystalline cellulose, natural mixed berry flavor, natural menthol flavor, polyethylene glycol, sodium lauryl sulfate, silicon dioxide, sodium starch glycolate, stevia, sucralose, talc.

Questions or Comments

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

Manufactured for and

Distributed by:

ProPhase Labs, Inc.

P.O. Box 1349, Doylestown

PA 18901

PRINCIPAL DISPLAY PANEL - Kit Carton

NEW QuickMelts®

GREAT

TASTE

Cold-EEZE®

Zinc Gluconate Glycine

COLD REMEDY

CLINICALLY PROVEN

INGREDIENT

Daytime

Nighttime

#1 Pharmacist Recommended

Daytime

☐ **Shortens your cold,
works faster™**

☐ **Non-drowsy**

Nighttime

- ▣ **Shortens your cold,
works faster™**
- ▣ **Fall asleep faster,
naturally**
- ▣ **Non-habit forming**

**18 MELTS
(Daytime)**

**QuickMelts®
Natural
Mixed Berry Flavor
Homeopathic**

**6 MELTS
(Nighttime)**

Do not use if carton seal is broken

18 Daytime Melts
6 Nighttime Melts
Natural Mixed Berry Flavor

Cold-EEZE
Zinc Gluconate Glycine
COLD REMEDY

Daytime
Nighttime **QuickMelts**[®]

NDC 61941-0225-4

Cold-EEZE
Zinc Gluconate Glycine
COLD REMEDY

QuickMelts[®]

NEW QuickMelts[®] **GREAT TASTE**

Cold-EEZE
Zinc Gluconate Glycine
COLD REMEDY

QuickMelts[®]

+ Dissolves quickly in the mouth without water

+ Releases zinc ions in the mouth

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

Manufactured for and Distributed by:
ProPhase Labs, Inc.
P.O. Box 1349, Doylestown
PA 18901
info@ProPhaseLabs.com

+ THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FDA AND DO NOT CONSTITUTE A CLAIM. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

Daytime
+ Shortens your cold, works faster[™]
+ Non-drowsy

Nighttime
+ Shortens your cold, works faster[™]
+ Fall asleep faster, naturally
+ Non-habit forming

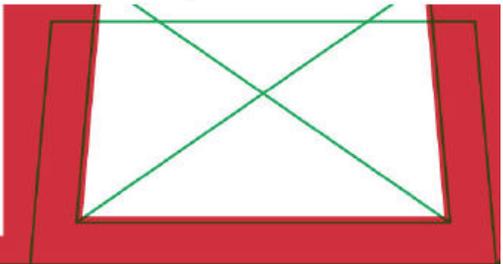
QuickMelts[®]
Natural Mixed Berry Flavor Homeopathic

18 MELTS (Daytime) **6 MELTS (Nighttime)**

Extra Strength Natural Nighttime Formula:
+ Chamomile and Valerian to help you relax and fall asleep faster, naturally
+ Shortens your cold, works faster[™]

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Cold-EEZE[®] Daytime QuickMelts[®] (AM)

Drug Facts	
Active ingredient (per tablet)	Purpose
Zincum Gluconicum 1X	Cold Remedy
Uses	
Take 1 QuickMelt every 2-4 hours per Directions on Inside panel.	
• 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, as zinc treatment may inhibit the absorption of these medicines.	
Cold-EEZE[®] Nighttime QuickMelts[®] (PM)	
Drug Facts	

- Continued -

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

Cold-EEZE[®] Nighttime QuickMelts[®] is a combination product formulated to help you to sleep easier and to reduce the duration of the common cold and its symptoms and is insufficient treatment for Influenza or Allergies.

Do not take Cold-EEZE[®] Nighttime QuickMelts[®] while operating a motor vehicle or machinery or consuming alcohol.

Allow 6-8 hours for sleep after taking tablet.

If pregnant or breast feeding, ask a healthcare practitioner before use.

Keep out of reach of children.

- Continued -

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

Cold-EEZE[®] QuickMelts[®] Daytime is formulated to reduce the duration of the common cold and its symptoms and is insufficient treatment for Influenza or Allergies.

If pregnant or breast feeding, ask a healthcare practitioner before use.

Keep out of reach of children.

Directions

- Take Cold-EEZE[®] Daytime QuickMelts[®] when you have cold symptoms
- Adults and Children 12 years and over:
 - Dissolve entire tablet in mouth. Do not chew. Do not swallow whole.

Active ingredients (per tablet) Zincum Gluconicum 1X Valeriana Officinalis 1X Chamomile (<i>Matricaria recutita</i>) 2X	Purpose Cold Remedy Sleep Disorder Remedy Relaxation and Calming	Directions <ul style="list-style-type: none"> Take Cold-EEZE® Nighttime QuickMelts® at night when you have cold symptoms. Adults: <ul style="list-style-type: none"> Dissolve entire tablet in mouth. Do not chew. Do not swallow whole. Take 1 Nighttime 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. For individuals under the age of 18, consult a healthcare practitioner before use. 	Do not swallow whole. <ul style="list-style-type: none"> Take 1 tablet at the onset of symptoms. Repeat every 2-4 hours as needed until all symptoms subside. Do not eat or drink for 15 minutes after use, otherwise, drink plenty of fluids. Recommended daily dose is 6 tablets for adults and 4 tablets for ages 12-17 years. *For children under 12 years of age, consult a healthcare practitioner before use.
Uses Take 1 Nighttime QuickMelt 1 hour before bedtime per Directions on Inside panel. <ul style="list-style-type: none"> 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. helps to relax and sleep easier to get rested. 		Other information <ul style="list-style-type: none"> Do not take Cold-EEZE® QuickMelts® on an empty stomach to avoid possible minor stomach upset. Store in a cool and dry place. 	Other information <ul style="list-style-type: none"> Do not take Cold-EEZE® QuickMelts® on an empty stomach to avoid possible minor stomach upset. Store in a cool and dry place.
Warnings Ask a doctor before using Cold-EEZE® Nighttime QuickMelts® if you <ul style="list-style-type: none"> 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. do not take concomitantly with loperamide. 		Inactive ingredients crospovidone, FD&C Blue #1 & #2, glycine, magnesium stearate, malic acid, maltodextrin, mannitol, microcrystalline cellulose, natural mixed berry flavor, natural menthol flavor, polyethylene glycol, sodium lauryl sulfate, silicon dioxide, sodium starch glycolate, stevia, sucralose, talc.	Inactive ingredients crospovidone, FD&C Red # 40, glycine, magnesium stearate, malic acid, mannitol, microcrystalline cellulose, natural mixed berry flavor, natural menthol flavor, polyethylene glycol, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, stevia, sucralose, talc.

- Continued -

Lift Corner



COLD-EEZE DAYTIME AND NIGHTTIME QUICKMELTS

zinc gluconate, valerian, and chamomile kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0225
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-0225-4	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	18
Part 2	1 BLISTER PACK	6

Part 1 of 2

COLD-EEZE DAYTIME QUICKMELTS

zinc gluconate tablet, orally disintegrating

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Gluconate (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	Zinc Gluconate	1 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
Glycine (UNII: TE7660XO1C)	
MALIC ACID (UNII: 817L1N4CKP)	
Crospovidone (UNII: 68401960MK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	PINK	Score	no score
Shape	OCTAGON (8 sided)	Size	15mm
Flavor	BERRY (MIXED BERRY)	Imprint Code	AM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		18 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		12/01/2014	

Part 2 of 2**COLD-EEZE NIGHTTIME QUICKMELTS**

zinc gluconate, valerian, and chamomile tablet, orally disintegrating

Product Information**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]
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	1 [hp_X]
Chamomile (UNII: FGL3685T2X) (Chamomile - UNII:FGL3685T2X)	Chamomile	2 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
Glycine (UNII: TE7660XO1C)	
MALIC ACID (UNII: 817L1N4CKP)	
Crospovidone (UNII: 68401960MK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OCTAGON (8 sided)	Size	15mm
Flavor	BERRY (MIXED BERRY)	Imprint Code	PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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		12/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		12/01/2014	

Labeler - ProPhase Labs, Inc. (620557298)

Establishment

Name	Address	ID/FEI	Business Operations
ProPhase Labs, Inc.		620557298	LABEL(61941-0225) , ANALYSIS(61941-0225) , REPACK(61941-0225)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	MANUFACTURE(61941-0225) , PACK(61941-0225) , REPACK(61941-0225)

Revised: 11/2014

ProPhase Labs, Inc.