

ULTRA COLD REMEDY RAPIDMELTS- zinc acetate and zinc gluconate tablet
Izeen Pharma, 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.

Ultra Zinc Cold Remedy Fast Melting -Cherry Flavor

Drug Facts

Active ingredients (in each tablet)

Zincum aceticum 2x
Zincum gluconicum 1x

Purpose

Reduces duration and severity of the common cold

Uses

- reduces duration of the common cold
- reduces the severity of cold symptoms:
 - sore throat
 - stuffy nose
 - sneezing
 - coughing
 - nasal congestion

Zicam[®] ULTRA Cold Remedy was formulated to shorten the duration of the common cold and was not formulated to be effective for flu or allergies.

Warnings

Ask a doctor before use if you have

- a sensitivity to zinc or are allergic to zinc

Stop use and ask a doctor if symptoms persist or are accompanied by fever

If pregnant or breast-feeding, ask a health 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

- **for best results, use at the first sign of a cold and continue to use until symptoms completely subside**
- adults and children 12 years of age and older:
 - take 1 tablet at the onset of symptoms
 - dissolve entire tablet in mouth. Do not chew. Do not swallow whole.
 - repeat every 4-6 hours, not to exceed 4 tablets in 24 hours
 - to avoid minor stomach upset, do not take on an empty stomach

- do not eat or drink for 15 minutes after use. Do not eat or drink citrus fruits or juices for 30 minutes before or after use. Otherwise, drink plenty of fluids.
- children under 12 years of age: ask a doctor before use

Other information

- store between 15-29° (59-84°F)

Inactive ingredients

artificial flavor, crospovidone, FD&C red no. 40 aluminum lake, magnesium stearate, mannitol, monoammonium glycyrrhizinate, sodium starch glycolate, stearic acid, sucralose

Questions/Comments

Questions/Comments call 1-844-287-0260

Manufactured by Izeen Pharma, Inc. 6900 English Muffin Way, Unit A, Frederick, MD 21703

PRINCIPAL DISPLAY PANEL - 18 Tablet Carton

NDC# 66007-103-18



ULTRA COLD REMEDY RAPIDMELTS

zinc acetate and zinc gluconate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66007-103
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	2 [hp_X]
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	1 [hp_X]

Inactive Ingredients	
Ingredient Name	Strength
CROSPVIDONE (UNII: 68401960MK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	PINK	Score	no score
Shape	ROUND	Size	15mm
Flavor	CHERRY	Imprint Code	Z
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66007-103-18	1 in 1 CARTON		
1		18 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		02/06/2015	

Labeler - Izeen Pharma, Inc. (079300974)

Establishment

Name	Address	ID/FEI	Business Operations
Izeen Pharma, Inc.		079300974	MANUFACTURE(66007-103)