

LUDENS ASSORTED FLAVORS- pectin lozenge
Prestige Brands Holdings, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Ludens Assorted Flavors

Drug Facts

Active ingredient (in each drop)

Pectin 2.8 mg

Purpose

Oral demulcent

Uses

For temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat.

Warnings

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.

Stop use and ask a doctor if

- sore mouth does not improve in 7 days
- irritation, pain or redness persists or worsens

Keep out of reach of children.

Directions

- **adults and children 3 years of age and older:** allow one drop to dissolve slowly in mouth.
- may be repeated as needed or as directed by a doctor
- **children under 3 years of age:** ask a doctor

Other information

store at 20°-25°C (68°-77°F) in a dry place

Inactive ingredients

Wild Cherry: ascorbic acid, citric acid, corn syrup, FD&C blue no. 2, FD&C red no. 40, flavors, malic acid, sodium acetate, sodium chloride, soybean oil, sucrose, water

Watermelon: ascorbic acid, citric acid, corn syrup, FD&C red no. 40, flavors, malic acid, sodium

acetate, sodium chloride, soybean oil, sucrose, water

Honey & Berry: caramel color, citric acid, corn syrup, FD&C blue no. 1, FD&C red no. 40, flavor, honey, sodium acetate, sodium chloride, soybean oil, sucrose, water

Questions?

1-866-583-3677 Ludens.com

PRINCIPAL DISPLAY PANEL

Luden's
 Pectin Lozenge/ Oral Demulcent
 Assorted flavors
 Wild Cherry • Watermelon • Honey & Berry
 90 Throat Drops



LUDENS ASSORTED FLAVORS

pectin lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52183-217
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
PECTIN (UNII: 89NA02M4RX) (PECTIN - UNII:89NA02M4RX)		PECTIN	2.8 mg	
Inactive Ingredients				
Ingredient Name		Strength		
ASCORBIC ACID (UNII: PQ6CK8PD0R)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
CORN SYRUP (UNII: 9G5L16BK6N)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
MALIC ACID (UNII: 817L1N4CKP)				
SODIUM ACETATE (UNII: 4550K0SC9B)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SOYBEAN OIL (UNII: 241ATL177A)				
SUCROSE (UNII: C151H8M554)				
WATER (UNII: 059QF0KO0R)				
CAMEL (UNII: T9D99G2B1R)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
HONEY (UNII: Y9H1V576FH)				
Product Characteristics				
Color	RED, YELLOW	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	FRUIT (Wild cherry, watermelon, honey & berry)	Imprint Code	LUDENS	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-217-90	90 in 1 BAG; Type 0: Not a Combination Product	06/13/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part356	06/13/2017		

Labeler - Prestige Brands Holdings, Inc. (159655021)

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Prestige Brands Holdings, Inc.