

LUDENS HONEY AND BERRY- 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 Honey and Berry

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

Inactive ingredients

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



LUDENS HONEY AND BERRY

pectin lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52183-212
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
CARAMEL (UNII: T9D99G2B1R)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HONEY (UNII: Y9H1V576FH)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW, PURPLE	Score	no score
Shape	CAPSULE	Size	22mm
Flavor	BLACKBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-212-25	25 in 1 BAG; Type 0: Not a Combination Product	07/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	07/01/2017	

Labeler - Prestige Brands Holdings, Inc. (159655021)