

LUDENS DUAL RELIEF- pectin and menthol 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 Dual Relief

Drug Facts

Active ingredient (in each drop)

Pectin 2.8 mg

Menthol 2.5 mg

Purpose

Oral demulcent

Cough suppressant

Uses

temporarily relieves:

- minor discomfort and protection of irritated areas in sore mouth and sore throat
- cough associated with a cold or inhaled irritants.

Warnings

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

Ask a doctor before use if you have

- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- cough lasts more than 7 days, tends to recur, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

Keep out of reach of children

Directions

- **adults and children 3 years of age and older:** allow two drops 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

corn syrup, FD&C blue no. 2, FD&C red no. 40, flavor, propylene glycol, sodium acetate, sodium chloride, soybean oil, sucrose, water

Questions?

1-866-583-3677 Ludens.com

Distributed by Medtech Products Inc.

Tarrytown, NY 10591

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PRINCIPAL DISPLAY PANEL

Luden's®

Cough Suppressant/Oral Demulcent

DUAL RELIEF

Wild Cherry

25 Cough Drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52183-227
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PECTIN (UNII: 89NA02M4RX) (PECTIN - UNII:89NA02M4RX)	PECTIN	2.8 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	22mm
Flavor	CHERRY (Wild Cherry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-227-25	25 in 1 BAG; Type 0: Not a Combination Product	06/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	06/15/2018	

Labeler - Prestige Brands Holdings, Inc. (159655021)