### LEGEND COUGH LOZENGE- menthol lozenge Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals

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.

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### **LEGEND**

### **Active Ingredient**

Menthol

### **Purpose**

Cough Suppressant/ Oral Anesthetic

### Uses

Temporarily suppresses/relieves:

- Coughs due to minor throat and bronchial irritation from a cold or inhaled irritant
- Occasional minor sore throat pain

### **Warnings**

### Ask a doctor before use if you have

- Chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis or emphysema
- Cough that occurs with too much phlegm (mucus)

### When using this product

**Do not use** more than directed, taking more may have a laxative effect

# Stop use and ask a doctor if

- Cough lasts more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These
  could be signs of a serious condition
- Sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, swelling, nausea or vomiting
- Sore mouth symptoms last more than 7 days, or irritation, pain or redness continues or worsens

### **Directions**

- Dissolve a lozenge slowly in mouth.
- May be repeated every hour for coughs as needed or as directed by a doctor.
- May be repeated every 2 hours for sore throat.
- Do not take more than 10 lozenges per day.

## Keep out of reach of children

- Adults and children 6 years and older 10 mg
- Children under 6 years ask a doctor

### **Inactive Ingredients**

Honey powder, Ginger extract, Licorice extract, Eucalyptol oil, Mexican Mint oil, Cinnamon oil, Mannitol, Sorbitol, Povidone K30, Xylitol, Silicone Dioxide, Magnesium stearate, Aspartame, Sucralose, Sodium benzoate, FD&C Yellow No. 5, FD&C Blue No. 1

# **Product Label**

Questions or comments? ccli 1-800-494-5560 (Mon - Fri 9 AM - 5PM PST)

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FOR COUGHS AND MINOR SORE THROAT PAIN

BETIC



Inactive Ingradients
Honey powder, Ginger extract, Licorice extract, Eucohyptol ol, Mexican Mint et. Chramon at, Mannital, Sarbital, Povidore K30, Xylital, Siscore Dodder, Magnesium searciale, Apparlame, Sucraiose, Sadium benzaarie, FD&C Yellow, No., 5, FD&C Bue No., 1

- SAFE

Active Ingredient (in each lazenge)
Menthal 10 mg..... Occasional minor sore throat pain Jose Temporarily suppresses/felieves:
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Adults and children

SUGAR FREE - DIABETIC - SAFE Menthol Suppressont/ Ord Anestheric CREEND

HARY TECEND

14941

ONERET

BAIG - BIRE - DIAB

**TEGEND** 

ONERED

DITERALD - SERT SAGUE

Oral Anesthetic

ONE BUCK - SITE BRANCE - STREET

GNS HAZ - DITH Om 04 Silestren's lost

MENTHOL - COUGH SUPPRESSANT/ORAL ANESTHETIC

**RUG FACTS** 

# Note: Batch No., Exp. date are print in the box and the blister. Marquette of Box: Box of 4 blisters x 6 lozenges

SINCE AQ BRANDS 2000

# Marquette of blister

Lot 51, Street 2. Ten Tao Industrial Park, Tan Tao A Ward, Binh Ten Dist.
S PM HCM City, Vielnam. Tel: (+84-28) 37507496 - Fax: (+84-28) 38771010

S.P.M CORPORATION

MARQUETTE FOR REGISTRATION

Khách hàng ký duyệt nội dung/quy cách

24 Lozenges x 6 lozenges)

(4 blisters

Nguyễn Hữu Trọng Duy

Box LEGEND Marquette

Phụ trách thiết kế

menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13411-842
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
HO NEY (UNII: Y9 H1V576 FH)		
GINGER (UNII: C5529G5JPQ)		
LICORICE (UNII: 61ZBX54883)		
EUCALYPTOL (UNII: RV6J6604TK)		
PLECTRANTHUS AMBO INICUS WHO LE (UNII: T444G60821)		
CINNAMON OIL (UNII: E5GY4I6 YCZ)		
MANNITOL (UNII: 30WL53L36A)		
Sorbitol (UNII: 506T60A25R)		
Povidone K30 (UNII: U725QWY32X)		
Xylitol (UNII: VCQ006KQ1E)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
Magnesium stearate (UNII: 70097M6I30)		
Aspartame (UNII: Z0H242BBR1)		
Sucralose (UNII: 96K6UQ3ZD4)		
Sodium benzoate (UNII: OJ245FE5EU)		
FD&C Yellow No. 5 (UNII: I753WB2F1M)		
FD&C Blue No. 1 (UNII: H3R47K3TBD)		

Product Characteristics			
Color	green (GREEN)	Score	no score
Shape	ROUND	Size	15mm
Flavor	MENTHOL	Imprint Code	
Contains			

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:13411-842-24	24 in 1 BOX; Type 0: Not a Combination Product	04/15/2020	

ı	Marketing Information			
l	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final part341 04/15/2020

Labeler - Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals (187498279)

Revised: 4/2020 Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals