

HONEY LEMON COUGH DROPS- menthol lozenge
InvaTech Pharma Solutions LLC

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.

Drug Facts

Active Ingredient

Menthol (From Mentha spicata) (in each 3gm Drop of Serving Size).....3.18 mg

Purposes

Soothing sore throats

Uses

- Natural way of calming cough and soothing sore throats

Warnings

Sore throat warnings: 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.

Do not use for children under 6 years of age unless directed by a doctor.

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore mouth does not improve in 7 days
- irritation, pain, or redness persist or worsens

Keep out of reach of children

Directions

- adults and children 6 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as if needed or as directed by a doctor
- children under 6 years: ask a doctor
- do not bite or chew

Other information

Protect from heat and moisture

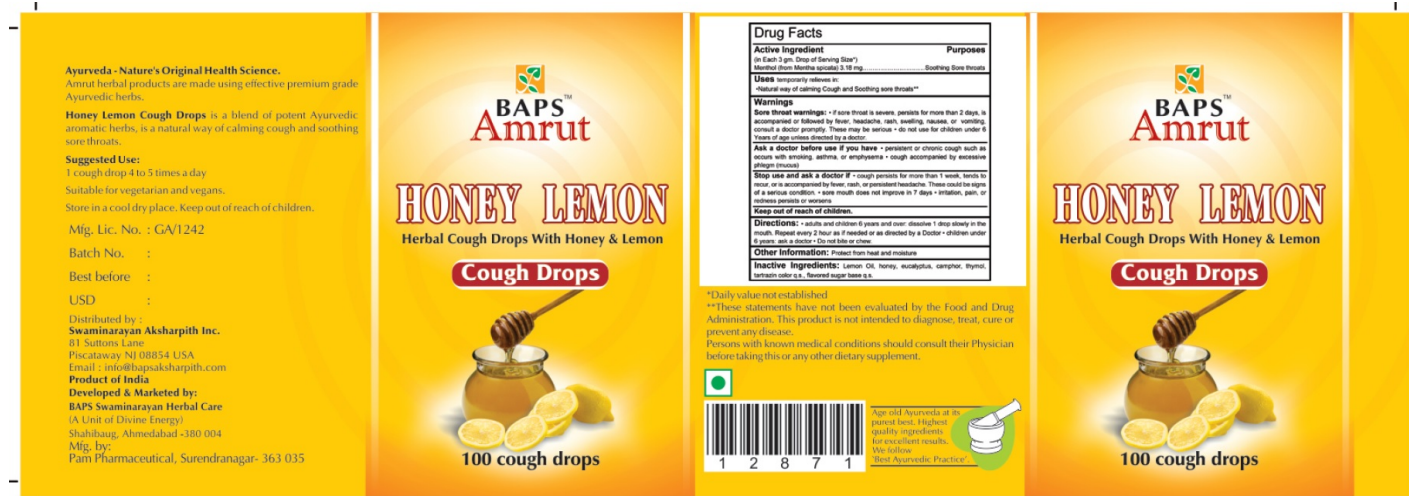
Inactive Ingredients

Lemon oil, honey, eucalyptus, camphor, thymol, tartrazin color q.s., flavored sugar base q.s.

OTC Principal Display Panel

Honey Lemon Cough Drops

100ct Bag



HONEY LEMON COUGH DROPS

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57631-130
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.18 mg

Inactive Ingredients

Ingredient Name	Strength
LEMON OIL (UNII: I9GRO824LL)	
HONEY (UNII: Y9H1V576FH)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
THYMOL (UNII: 3J50XA376E)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	18 mm

Flavor	HONEY		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57631-130-71	100 in 1 PACKAGE; Type 0: Not a Combination Product	10/31/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/31/2017		

Labeler - InvaTech Pharma Solutions LLC (078602180)

Establishment

Name	Address	ID/FEI	Business Operations
BAPS Swaminarayan Herbal Care, A Unit of Divine Energy		921183294	manufacture(57631-130) , pack(57631-130)

Revised: 12/2018

InvaTech Pharma Solutions LLC