ORGANIX COMPLETE- menthol and pectin lozenge ProPhase Labs, 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.

Organix Complete Cough & Sore Throat Drops

Drug Facts

Active ingredients (in each drop)	Purposes
Menthol 2.5mg	cough suppressant, oral anesthetic
Pectin 1.7mg	oral demulcent

Uses

temporarily relieves:

- cough associated with a cold or inhaled irritants
- occasional minor irritation, pain, 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. Do not give to children under 5 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 lasts more than 1 week, tends to reoccur, 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 persists or worsens

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children.

Directions

- adults and children 5 years and older: Dissolve 2 drops (one at a time) slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor

Other information

• store in a cool dry place after opening

Inactive ingredients

natural flavors, organic caramel color, organic evaporated cane juice, organic hyssop, organic marshmallow root, organic mullein, organic peppermint oil, organic sage, organic slippery elm, organic sunflower oil, organic tapioca syrup, organic thyme, sucrose

Questions? Comments?

Call 1-800-505-2653 9am-5pm Eastern

PRINCIPAL DISPLAY PANEL - 21 Drop Package

Multi Symptom Relief

ORganix[™] COMPLETE

Cough & Sore Throat Drops

Menthol (from Peppermint Oil) - Cough Suppressant Pectin - Oral Demulcent

Mint Chocolate

Flavor

MADE WITH 70% ORGANIC INGREDIENTS

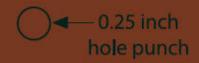
Suppresses Coughs

Soothes Sore Throats

Blend of 6 Organic Herbs

Gluten Free

21 Drops



Multi Symptom Relief

Cough & Sore Throat Drops

Menthol (from Peppermint Oil) - Cough Suppressant

Pectin - Oral Demulcent

Mint Chocolate

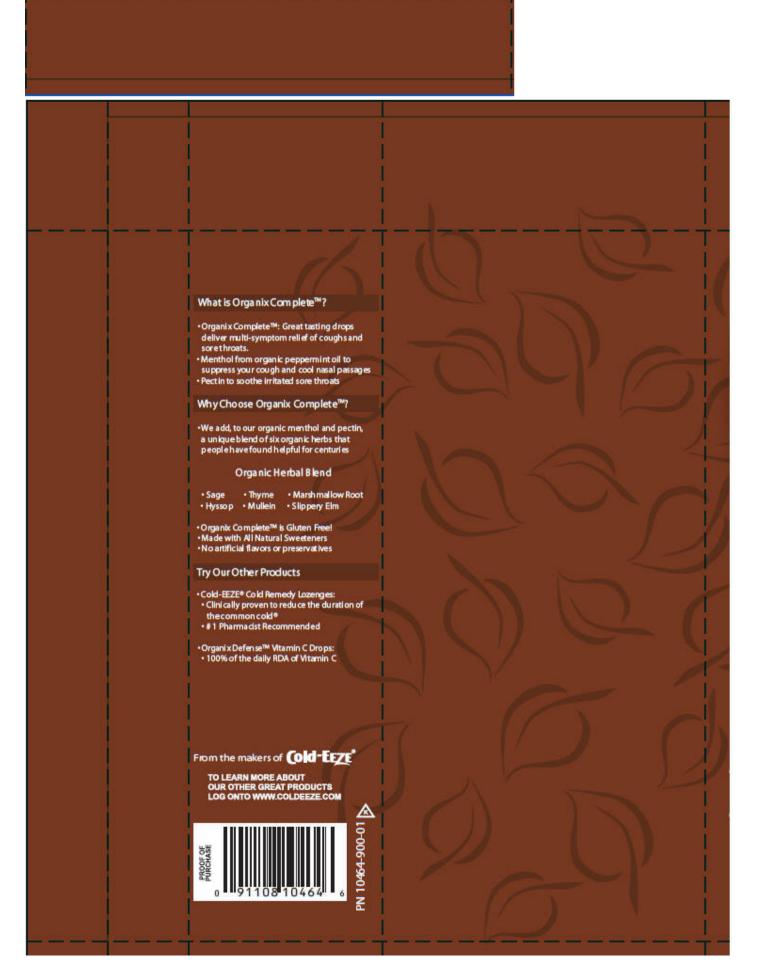


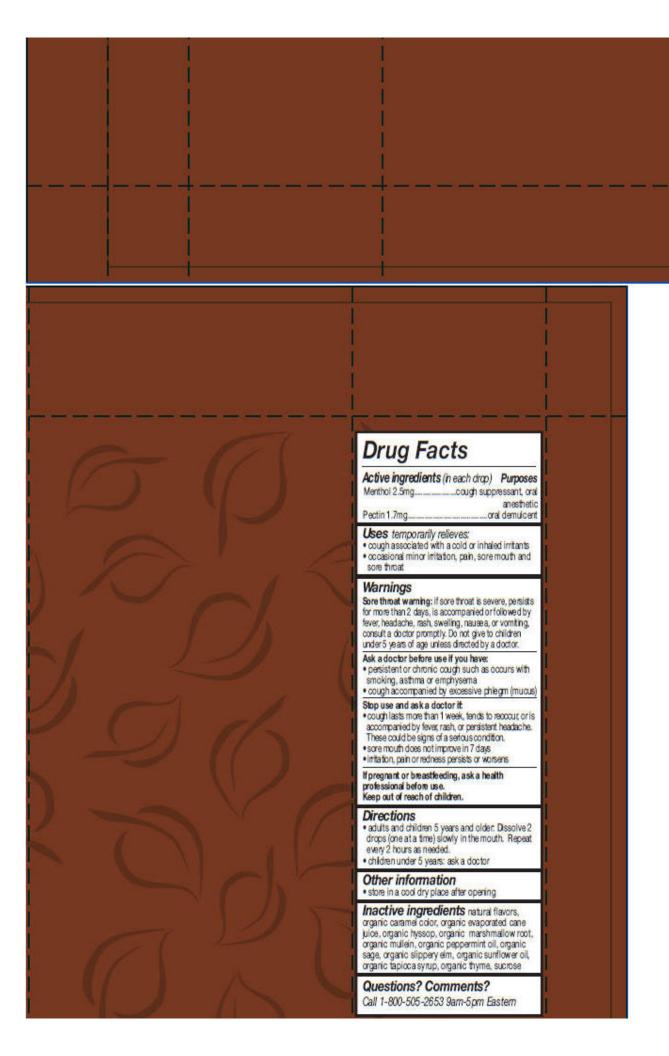
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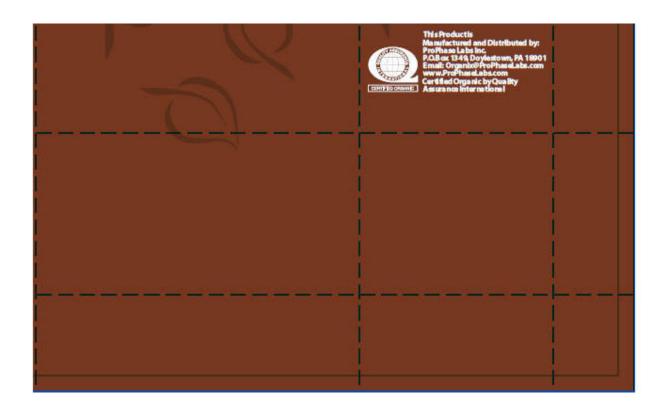
21 Drops











ORGANIX COMPLETE

menthol and pectin lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-0132
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Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	2.5 mg
Pectin (UNII: 89 NA0 2M4RX) (Pectin - UNII:89 NA0 2M4RX)	Pectin	1.7 mg

Inactive Ingredients			
Strength			

Product Characteristics

Color	BROWN (Semi-Translucent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	CHOCOLATE (Mint Chocolate)	Imprint Code	P
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-0132-2	48 in 1 CASE		
1	NDC:61941-0132-1	21 in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/0 1/20 10	

Labeler - ProPhase Labs, Inc. (620557298)

Establishment			
Name	Address	ID/FEI	Business Operations
Pro Phase Labs, Inc.		620557298	LABEL, ANALYSIS

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	MANUFACTURE, ANALYSIS, PACK, REPACK

Revised: 4/2011 ProPhase Labs, Inc.