

COUGH DROP- menthol lozenge
NORTH COUGH DROP- menthol lozenge
Honeywell Safety Products USA, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

0498-1120, 0498-0119 & 0498-1119: Cough Drops

Active ingredient (in each drop)

Menthol 7 mg

Purpose

Cough suppressant /oral anesthetic

Uses

temporarily relieves

- cough as may occur with a cold or inhaled irritants
- occasional minor irritation, pain, sore mouth and sore throat

Warnings

Sore throat warning: if sore throat is severe, lasts for more than 2 days, is accompanied or followed by a fever, headache, rash, swelling, nausea or vomiting, consult a doctor promptly

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

- a persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache.
- irritation, pain, or redness persist or worsen

If pregnant or breast feeding:

- ask a health professional before use

Keep this and all drugs out of the reach of children

Enter section text here

Directions

- adults and children 2 years of age and over
- dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed
- children under 2 years of age: ask a doctor

Other information

- gluten free
- 15 calories per cough drop
- store at room temperature
- protect from moisture
- soybean oil used as a processing aid
- do not use if wrapper is open

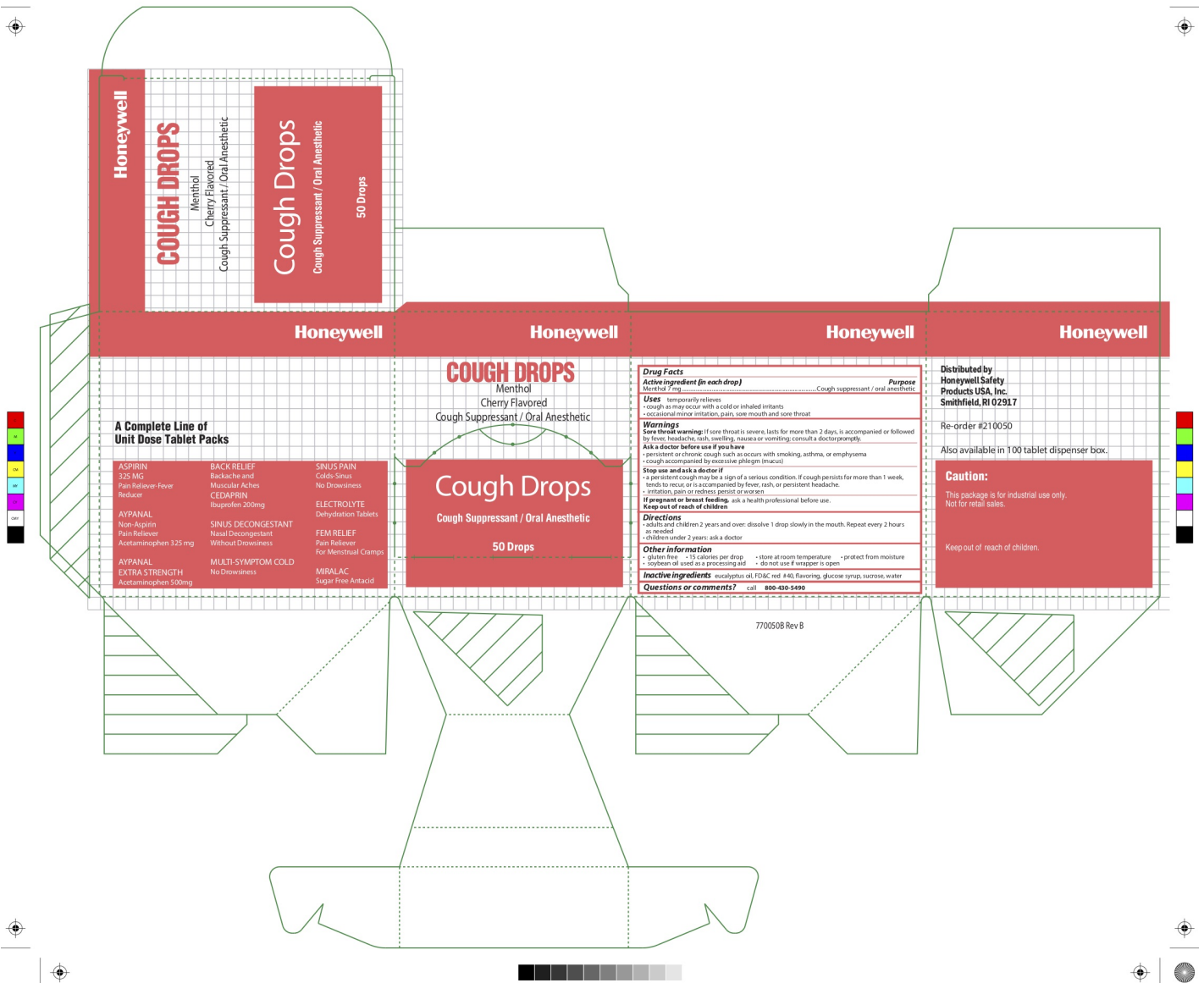
Inactive ingredients

eucalyptus oil, FD &C red #40, flavoring, glucose syrup, sucrose, water


Questions or comments?

call 800-430-5490

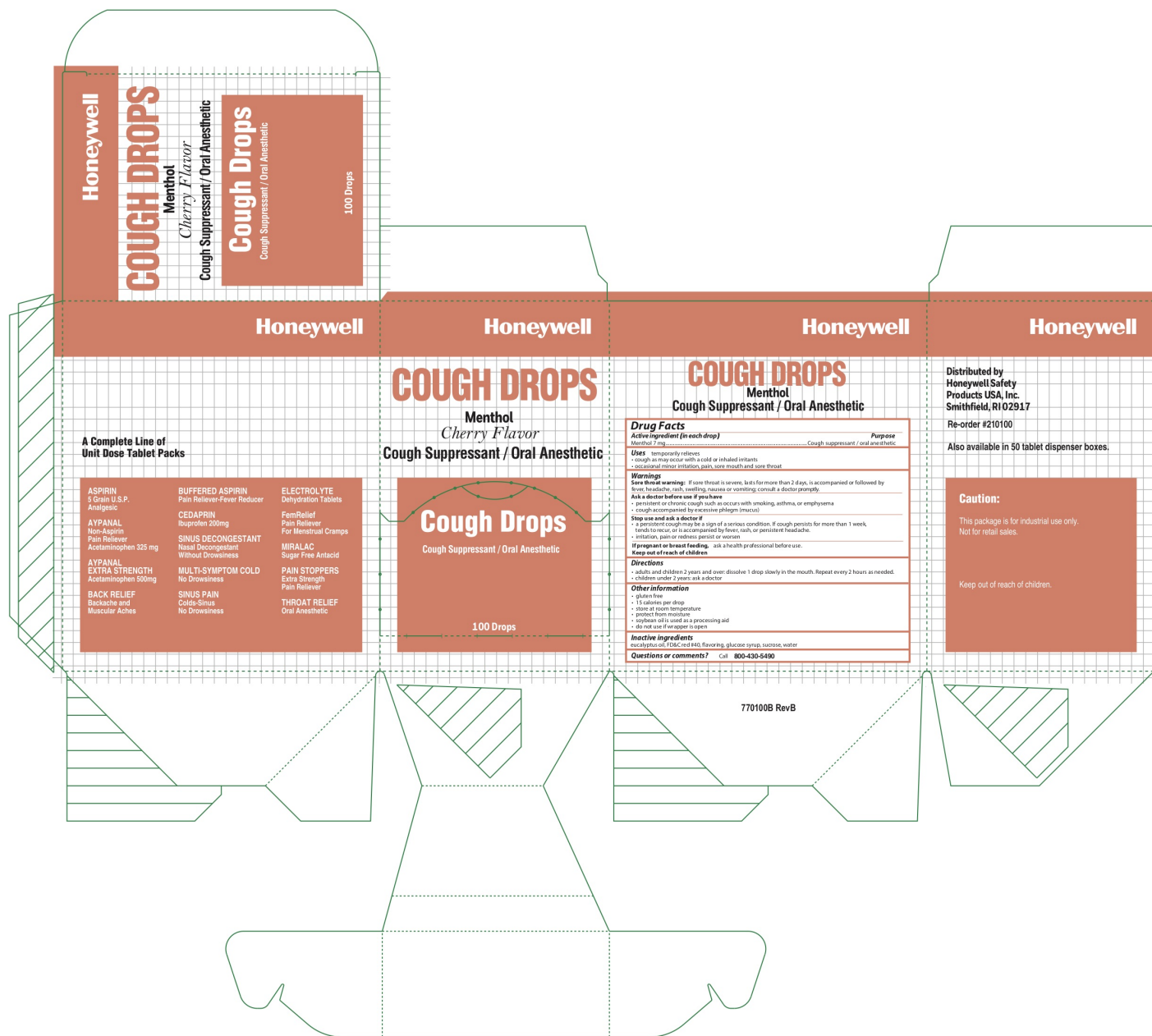
Principal Display Panel



Cough drops original

NORTH by Honeywell		NORTH by Honeywell					
<h1>COUGH DROPS</h1> <p><i>Cherry Flavored</i> <i>Menthol Cough Suppressant</i></p>  <div> <h2>Cough Drops</h2> <p>Menthol Cough Suppressant</p> <p>Quantity 50 Tablets</p> </div>		<h3>Drug Facts</h3> <table border="1"> <thead> <tr> <th>Active ingredient (in each drop)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Menthol 7.0 mg</td> <td>Cough suppressant / Oral anesthetic</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves cough as may occur with a cold or inhaled irritants occasional minor irritation, pain, sore mouth and sore throat <p>Warnings</p> <p>Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash or nausea or vomiting, consult a doctor promptly.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> persistent or chronic cough such as occurs with smoking, asthma, or emphysema cough accompanied by excessive phlegm (mucus) <p>When using this product:</p> <ul style="list-style-type: none"> do not exceed recommended dosage <p>Stop use and consult doctor if:</p> <ul style="list-style-type: none"> cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headaches. These could be signs of a serious condition. sore mouth symptoms do not improve in 7 days <p>If pregnant or breast feeding</p> <ul style="list-style-type: none"> ask a health professional before use. <p>Keep this and all drugs out of the reach of children</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 2 years of age and over dissolve drop slowly in the mouth repeat every 2 hours as needed or as directed by a doctor. children under 2 years of age: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> 15 calories per drop: gluten free: store at room temperature protect from moisture do not use if individual wrapper is open soybean oil used as a processing aid <p>Inactive ingredients glucose syrup, eucalyptus oil, n&h flavoring, red no. 40, sucrose and water.</p> <p>Questions or comments? call 800-430-4110</p>		Active ingredient (in each drop)	Purpose	Menthol 7.0 mg	Cough suppressant / Oral anesthetic
Active ingredient (in each drop)	Purpose						
Menthol 7.0 mg	Cough suppressant / Oral anesthetic						

Honeywell Cough Drop Label



COUGH DROP

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-1120
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-1120-00	1 in 1 POUCH; Type 0: Not a Combination Product	09/18/2018	
2	NDC:0498-1120-05	50 in 1 BOX; Type 0: Not a Combination Product	09/18/2018	
3	NDC:0498-1120-10	100 in 1 BOX; Type 0: Not a Combination Product	09/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

NORTH COUGH DROP

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-0119
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7 mg

Inactive Ingredients

Ingredient Name	Strength
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CORN SYRUP (UNII: 9G5L16BK6N)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0119-00	1 in 1 POUCH; Type 0: Not a Combination Product	12/18/2017	12/31/2017
2	NDC:0498-0119-05	50 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	12/18/2017	12/31/2017
3	NDC:0498-0119-07	100 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	08/24/2013	12/31/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2013	12/31/2017

NORTH COUGH DROP

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-1119
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	

EUCALYPTUS OIL (UNII: 2R04ONI662)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
SUCROSE (UNII: C151H8M554)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	red (RED)		Score	no score
Shape	OVAL		Size	22mm
Flavor	CHERRY (CHERRY)		Imprint Code	B
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-1119-00	1 in 1 POUCH; Type 0: Not a Combination Product	01/02/2017	09/18/2018
2	NDC:0498-1119-05	50 in 1 BOX; Type 0: Not a Combination Product	01/02/2017	09/18/2018
3	NDC:0498-1119-10	100 in 1 BOX; Type 0: Not a Combination Product	01/02/2017	09/18/2018
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			08/24/2013	09/18/2018

Labeler - Honeywell Safety Products USA, Inc (118768815)

Registrant - Honeywell Safety Products USA, Inc (118768815)