

COUGH DROPS- menthol pastille
United Natural Foods, 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.

Cough Drops

Active Ingredient

- Menthol 7.5 mg cough suppressant oral anesthetic
-



◀ Tear here ----- Tear here ▶

Resealable Bag

1. Tear 2. Separate to open 3. Press to reseal

EQUALINE[®]

compare to Halls[®]
active ingredient[†]

honey-lemon

cough drops

menthol - cough
suppressant/
oral anesthetic

- temporarily relieves cough
- soothes sore throat pain
- no artificial flavors
- no synthetic dyes





30 drops

honey-lemon flavor
*actual size depiction on back

Uses temporarily relieves:

- cough as may occur with a cold
- occasional minor irritation and sore throat

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Warnings

Sore throat warning: severe or persistence sore throat accompanied by high fever, headache, nausea and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 12 years of age.

Ask a doctor before use if you have

- a severe throat accompanied by difficulty in breathing or that last more than 2 days
- a sore throat accompanied by fever, headache, rash, swelling, nausea or vomiting

Stop use and consult a doctor if

- sore mouth symptoms do not improve in 7 days or if irritation, pains or redness persists or worsens.

If pregnant or breast-feeding, ask a health professional before use.

Keep this and all drugs out of the reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years and over: dissolve 1 drop slowly in mouth. Repeated every 2 hours as needed or as directed by a doctor.
- Children under 12 years and under do not use
- Store in a cool and dry plac
- 10 calories per drop

citric acid, flavors, glucose syrup, honey, sucrose, turmeric (for color)

Questions or comments: 1-855-423-2630

1. Tear 2. Separate to open 3. Press to reseal

EQUALINE®

menthol
cough drops



*Actual Size

* This product is not manufactured or distributed by Mondelez Global LLC, owner of the registered trademark Halls®.

DISTRIBUTED BY UNFI
PROVIDENCE, RI 02908 USA
PRODUCT OF SPAIN
GLUTEN FREE
DO NOT USE IF BAG IS TORN OR OPEN.



Like it or let us make it right.
That's our quality promise.
855-423-2630



09427.1

Leave blank for
LOT / EXP. DATE

<p>Drug Facts</p> <p>Active ingredient (in each drop) Purposes Menthol 5.4 mg cough suppressant, oral anesthetic</p> <p>Uses temporarily relieves: <ul style="list-style-type: none"> ■ cough as may occur with a cold. ■ occasional minor irritation and sore throat. </p>	
<p>Warnings Sore throat warning: Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 12 years of age.</p> <p>Ask a doctor before use if you have <ul style="list-style-type: none"> ■ a severe throat accompanied by difficulty in breathing or that lasts more than 2 days. ■ a sore throat accompanied by fever, headache, rash, swelling, nausea or vomiting. </p> <p>When using this product <ul style="list-style-type: none"> ■ do not exceed recommended dosage. </p> <p>Stop and consult a doctor if <ul style="list-style-type: none"> ■ sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens. </p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
<p>Directions <ul style="list-style-type: none"> ■ Adults and children 12 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed or as directed by a doctor. ■ Children under 12 years: do not use. </p>	
<p>Other information ■ 10 calories per drop. <ul style="list-style-type: none"> ■ Store in a cool and dry place. </p>	
<p>Inactive ingredients Glucose syrup, sucrose.</p>	
<p>Questions? Or to report an adverse event call 1-855-423-2630.</p>	



COUGH DROPS

menthol pastille

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83455-203
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7.5 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
HONEY (UNII: Y9H1V576FH)	
SUCROSE (UNII: C151H8M554)	
TURMERIC (UNII: 856YO1Z64F)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	yellow (Transparent)	Score	score with uneven pieces
Shape	OVAL	Size	25mm
Flavor	HONEY (Lemon)	Imprint Code	None
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83455-203-01	30 in 1 BAG; Type 0: Not a Combination Product	05/12/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/12/2023	

Labeler - United Natural Foods, Inc. (943556183)

Registrant - Boston Nutraceutical Science SL (466061824)

Establishment

Name	Address	ID/FEI	Business Operations
Boston Nutraceutical Production SL		468121064	manufacture(83455-203) , label(83455-203) , pack(83455-203)

Revised: 5/2023

United Natural Foods, Inc.