

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 5.8 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*

sugar free menthol

**cough
drops**

menthol - cough
suppressant/
oral anesthetic

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



140 drops

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

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 place
- 5 calories per drop
- Maybe useful for diabetics on the advice of a doctor
- Excess consumption may cause laxative effect

citric acid, isomalt, stevia

Questions or comments: 1-855-423-2630

COUGH DROPS
menthol pastille

▶ Tear here ----- ▶ Tear here

Resealable Bag

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

EQUALINE®

sugar free menthol
cough drops



*Actual Size

‡ This product is not manufactured or distributed by Mondelēz 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.

100% Quality GUARANTEED
Like it or let us make it right.
That's our quality promise.
855-423-2630



Leave blank for
LOT / EXP. DATE

09/23/1

<p>Active ingredient (in each drop) Purposes Menthol 5.8 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. 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 ■ 5 calories per drop. <ul style="list-style-type: none"> ■ May be useful for diabetics on the advice of a doctor. ■ Excess consumption may cause laxative effect. ■ Store in a cool and dry place. </p>	
<p>Inactive ingredients Citric acid, isomalt, stevia.</p>	
<p>Questions? Or to report an adverse event call 1-855-423-2630.</p>	

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83455-205
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.8 mg

Inactive Ingredients

Ingredient Name	Strength
STEVIA LEAF (UNII: 6TC6NN0876)	
ISOMALT (UNII: S870P55O2W)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83455-205-01	140 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(83455-205) , label(83455-205) , pack(83455-205)