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 suppresant oral anesthetic



Resealable Bag

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

EQUALINE®

compare to Halls® active ingredient*

sugar free menthol

cough

menthol - cough suppressant/ oral anesthetic

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





Uses temporarily relieves:

- cough as may occur with a cold
- ocassional 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 symptons 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 comsuption may cause laxative effect

citric acid, isomalt, stevia

EONTINE

sugar free menthol

drops ugnoo



*Actual Size

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

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



822-452-5630 That's our quality promise. Like it or let us make it right.

Drug Facts

Menthol 5.8 mg cough suppressant, oral anesthetic Active ingredient (in each drop) Purposes

USes temporarily relieves:

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

Warnings

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

Ask a doctor before use if you have

- a severe throat accompanied by difficulty in breathing or
- a sore throat accompanied by fever, headache, rash, that lasts more than 2 days.
- swelling, nausea or vomiting.
- When using this product
- do not exceed recommended dosage.
- Stop and consult a doctor if
- irritation, pain, or redness persists or worsens. ■ sore mouth symptoms do not improve in 7 days, or if

Center right away. overdose, get medical help or contact a Poison Control before use. Keep out of the reach of children. In case of If pregnant or breast-feeding, ask a health professional

Directions

directed by a doctor. 2 hours as needed or as the mouth. Repeat every years and over: dissolve 1 drop slowly in St nehildren 12

■ Children under 12 years:

Other information • 5 calories per drop.

- May be useful for diabetics on the advice of a doctor.
- Store in a cool and dry place. Excess consumption may cause laxative effect.

Inactive ingredients Citric acid, isomalt, stevia.

Questions? Or to report an adverse event call



LOT / EXP. DATE Leave blank for



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> than 2 days or administer to children under 12 years of age. may be serious. Consult doctor promptly. Do not use more accompanied by high fever, headache, nausea, and vomiting

Ask a doctor before use if you have

- a severe throat accompanied by difficulty in breathing or
- a sore throat accompanied by fever, headache, rash, that lasts more than 2 days.

When using this product swelling, nausea or vomiting.

do not exceed recommended dosage.

- Stop and consult a doctor if
- sore mouth symptoms do not improve in 7 days, or if
- irritation, pain, or redness persists or worsens.

Center right away. overdose, get medical help or contact a Poison Control before use. Keep out of the reach of children. In case of If pregnant or breast-feeding, ask a health professional

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■ Children under 12 years: |

Other information • 5 calories per drop.

- Excess consumption may cause laxative effect. May be useful for diabetics on the advice of a doctor.
- Store in a cool and dry place.

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LOT / EXP. DATE Leave blank for

Questions or comments: 1-855-423-2630

Resealable Bag - — Tear here | ■ Tear here

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

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

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

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

Product Type HUMAN OTC DRUG Item Code (Source)

NDC:83455-204

Product Information

COUGH DROPS

menthol pastille

Route of Administration

ORAL

Active Ingredient/Active Moiety

Tear here

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Resealable Bag

ESOALINE

sugar free menthol

cough

Drug Facts

Menthol 5.8 mg cough suppressant, oral anesthetic Purposes Active ingredient (in each drop)

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Contains

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:83455-204- 01	25 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(83455-204) , label(83455-204) , pack(83455- 204)	

Revised: 5/2023 United Natural Foods, Inc.