

**COUGH DROPS- simply menthol cough drops pastille
Perrigo Direct, 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.

Simply menthol Cough Drops

Active Ingredient

- Menthol 5.4 mg cough suppressant oral anesthetic

◀ Tear here ----- Tear here ▶

Resealable Bag

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

GOODSENSE®

50804-XXX-XX

Healthy & Soothing

SIMPLY MENTHOL

Cough Drops



Menthol Cough Suppressant / Oral Anesthetic

- **Soothes Sore Throat Pain**
- **Temporarily Relieves Cough**

NO ARTIFICIAL COLORS
NO ARTIFICIAL FLAVORS





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 place
- 10 calories per drop
- glucose syrup, sucrose

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GLUTEN FREE
GMO FREE



Actual Piece Size

Distributed by:
Perrigo Direct, Inc.
Peachtree City, GA 30269
www.PerrigoDirect.com
1-833-552-1767
GoodSense® is a registered
trademark of L. Perrigo Company.
MADE IN SPAIN

† This product is not
manufactured or distributed by
Mondelēz International, owner of
the registered trade mark "Halls".

<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. Ask a doctor before use if you have <ul style="list-style-type: none"> ■ a severe cough 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. ■ Store in a cool and dry place.</p>	
<p>Inactive ingredients Glucose syrup, sucrose.</p>	
<p>Questions? Or to report an adverse event call 1-833-552-1767.</p>	

09494.1



Resealable Bag

◀ Tear here --- Tear here ▶



Questions or comments: 1-855-423-2630



09494.1

■ OCCASIONAL MILD IRRITATION AND SORE THROAT.

Warnings 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

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

When using this product

- 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.

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COUGH DROPS

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-592
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.4 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
SUCROSE (UNII: C151H8M554)	

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:50804-592-01	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 - Perrigo Direct, Inc. (076059836)

Registrant - Boston Nutraceutical Science SL (466061824)

Establishment

Name	Address	ID/FEI	Business Operations
Boston Nutraceutical Production SL		468121064	manufacture(50804-592) , label(50804-592) , pack(50804-592)

Revised: 5/2023

Perrigo Direct, Inc.