COUGH DROPS- menthol pastille The Kroger CO

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 5.4 mg
Cough Suppressant
Oral anesthetic





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.

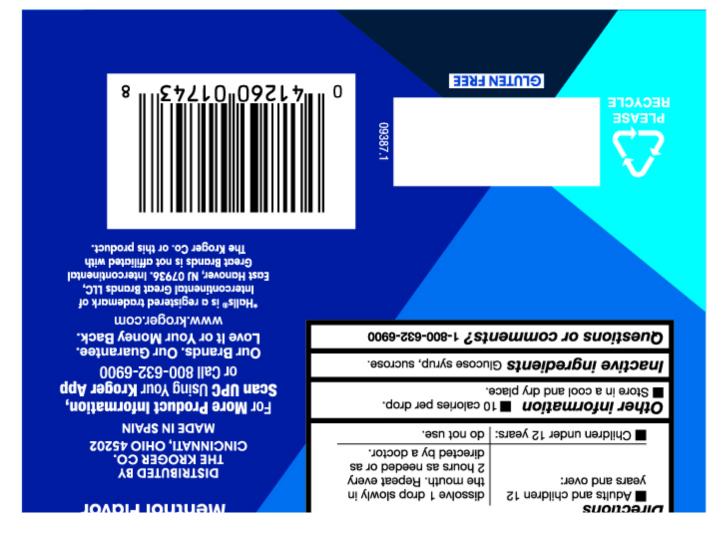
Keep this and all drugs out of the reach of children.

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

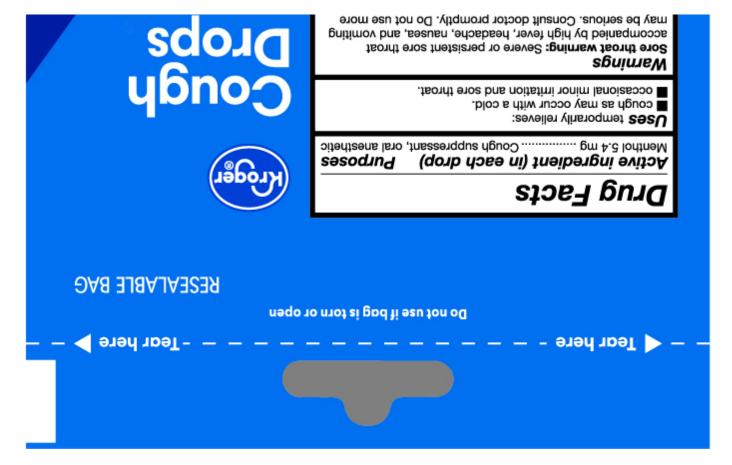
Directions

- 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
- 10 calories per drop





Questions or comments: 1-800-632-6900



Product Information Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:59450-713 **ORAL Route of Administration**

COUGH DROPS

menthol pastille

Tear here

Tear here

KESEALABLE BAG

Do not use if bag is torn or open

Purposes

or Preservatives

Flavors, Colors

No Artificial

than 2 days or administer to children under 12 years of age. may be serious. Consult doctor promptly. Do not use more

Ask a doctor before use if you have

accompanied by high fever, headache, nausea, and vomiting Sore throat warning: Severe or persistent sore throat

Menthol 5.4 mg Cough suppressant, oral anesthetic

a severe throat accompanied by difficulty in breathing or

that lasts more than 2 days.

swelling, nausea or vomiting. a sore throat accompanied by fever, headache, rash,

do not exceed recommended dosage. When using this product

occasional minor irritation and sore throat.

Active ingredient (in each drop)

 cough as may occur with a cold. USes temporarily relieves:

Orug Facts

■ sore mouth symptoms do not improve in 7 days, or if Stop and consult a doctor if

irritation, pain, or redness persists or worsens.

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

Center right away.

Warnings

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

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

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:59450-713- 01	30 in 1 BAG; Type 0: Not a Combination Product	12/13/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/13/2022	

Labeler - The Kroger CO (006999528)

Registrant - Boston Nutraceutical Science SL (466061824)

Establishment			
Name	Address	ID/FEI	Business Operations
Boston Nutraceutical Production SL		468121064	manufacture(59450-713) , label(59450-713) , pack(59450-713)

Revised: 12/2022 The Kroger CO