COUGH DROPS- menthol pastille Topco Associates LLC

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.

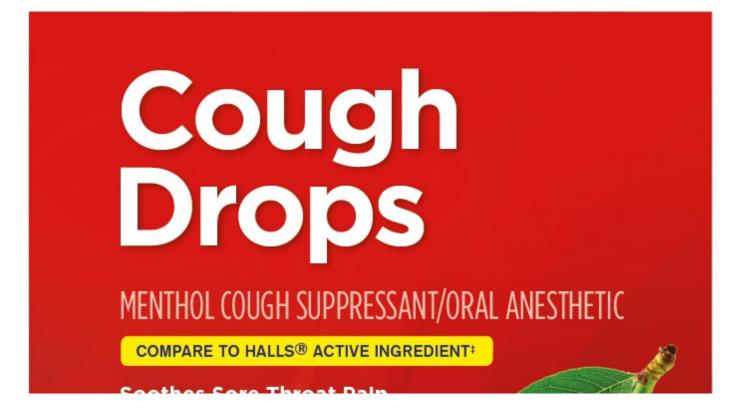
Cough Drops

Active ingredient 5.8 mg
Cough Suppressant
Oral anesthetic

RESEALABLE BAG

Tear here







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

blackcurrant, blackcarrot, citric acid, glucose syrup, sucrose

Questions? or to report and adverse event call: 1-800-423-0139



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

occasional minor irritation and sore throat.

USes temporarily relieves:

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

Drug Facts



 No Artificial Flavors, Preservatives

Soothes Sore Throat Pain & Temporarily Relieves Cough

MENTHOL COUGH SUPPRESSANT/ ORAL ANESTHETIC



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RESEALABLE BAG

COUGH DROPS

menthol pastille

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-014

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)

MENTHOL

5.8 mg

Inactive Ingredients

| 3 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | |
|---|----------|--|
| Ingredient Name | Strength | |
| SUCROSE (UNII: C151H8M554) | | |
| BLACK CURRANT (UNII: 9755T40D11) | | |
| BLACK CARROT (UNII: 27793ZFD2L) | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | |
| CORN SYRUP (UNII: 9G5L16BK6N) | | |

Product Characteristics

| Color | red | Score | score with uneven pieces |
|----------|--------|--------------|--------------------------|
| Shape | OVAL | Size | 25mm |
| Flavor | CHERRY | Imprint Code | None |
| Contains | | | |

| P | ackaging | | | | |
|---|----------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | NDC:76162-014- | 30 in 1 BAG; Type 0: Not a Combination | 12/14/2022 | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 12/14/2022 | |
| | | | |

Labeler - Topco Associates LLC (006935977)

Registrant - Boston Nutraceutical Science SL (466061824)

| Establishment | | | | |
|------------------------------------|---------|-----------|---|--|
| Name | Address | ID/FEI | Business Operations | |
| Boston Nutraceutical Production SL | | 468121064 | label(76162-014) , pack(76162-014) , manufacture(76162-014) | |

Revised: 12/2022 Topco Associates LLC