MENTHOL VAPOR COUGH DROPS- menthol pastille BOSTON NUTRACEUTICAL PRODUCTION, S.L

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.

Menthol Vapo Cough Drops Severe

Menthol Cough Suppressant 20 mg MENTHOL per drop/ Oral Anesthetic

Active Ingredient in each drop Purposes

Menthol 20 mg

Severe

Menthol Caugh Suppressant

Oral Anesthetic

Purposes

Temporarily relieves ocassional minor irritation and pain due to:

- sore throat
- sore mouth

Purposes

Temporarily relieves ocassional minor irritation and pain due to:

- sore throat
- sore mouth

Warnings

Sore throat warning: severe or persistent throat accompanied by high fever headache, nausea and vomiting maybe serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 12 years of old.

Ask a doctor before use if you have

- A severe throat accompanied by difficulty in breathing or that last more than 2 days
- A severe throat accompanied by fever, headache, rash, swealling, nausea or vomiting.

Stop use and consult doctor if

 sore mouth symptons does not improve in 7 days or if irritation, pain or redness persists or worse

If pregnant or breast feeding, ask a health professional before use.

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.

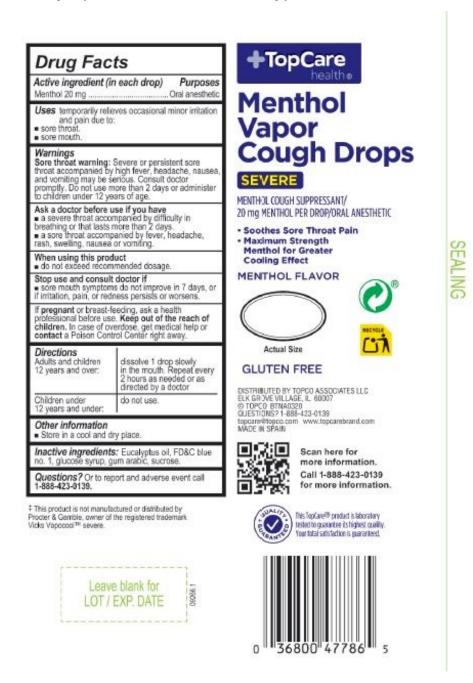
Directions

- Adults and children 12 years and over: dissolve 1 drop slowly in mouth. Repeated every two hours as needed or as directed by a doctor.
- Children 12 years or under do not use

Other information

• Store in a cool and dry place

corn syrup, sucrose, water, eucalyptus oil, acacia, FD&Blue No.1



Questions or comments call: 1-888-423-0139



MENTHOL VAPOR COUGH DROPS

menthol pastille

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72628-108 |
| Route of Administration | ORAL | | |
| | | | |

| Active Ingredient/Active Moiety | | |
|---------------------------------|-------------------|----------|
| Ingredient Name | Basis of Strength | Strength |

| Inactive Ingredients | | |
|------------------------------------|----------|--|
| Ingredient Name | Strength | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | | |
| SUCROSE (UNII: C151H8M554) | | |
| WATER (UNII: 059QF0KO0R) | | |
| CORN SYRUP (UNII: 9G5L16BK6N) | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | |
| ACACIA (UNII: 5C5403N260) | | |

| Product Characteristics | | | |
|-------------------------|-----------------------------------------|--------------|--------------------------|
| Color | blue (Clear with internal blue glitter) | Score | score with uneven pieces |
| Shape | OVAL | Size | 25mm |
| Flavor | MENTHOL (and eucalyptus) | Imprint Code | Р |
| Contains | | | |

| ı | Packaging | | | | |
|---|-----------|----------------------|------------------------------------------------|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:72628-108- 01 | 45 in 1 BAG; Type 0: Not a Combination Product | 06/01/2020 | |

| Marketing Information | | | |
|-----------------------|---------------------------------------------|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 06/01/2020 | |
| | | | |

Labeler - BOSTON NUTRACEUTICAL PRODUCTION, S.L (468121064)

Registrant - Boston Nutraceutical Science SL (466061824)

| Establishment | | | |
|---------------------------------------|---------|-----------|-------------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| BOSTON NUTRACEUTICAL PRODUCTION, S.I. | | 468121064 | manufacture(72628-108) . label(72628-108) |

Revised: 2/2023 BOSTON NUTRACEUTICAL PRODUCTION, S.L