MGC HEALTH- cough drops menthol sugar-free lozenge YUNNAN BAIYAO GROUP CO., LTD

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.

YNBY-MGC Cough Drops Menthol Sugar-Free 25

Active Ingredient(s)

Menthol 5.4 mg

Purpose

Purposes cough suppressant, oral anesthetic

Use

temporary relieves: ■ cough due to cold ■ occasional minor irritation or sore throat

Warnings

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or follow headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.

Ask a doctor before use if you have: \blacksquare persistent or chronic cough such as occurs with smoking, asthma, or emphysema \blacksquare cough accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if \blacksquare cough persists for more than 1 week, tends to recur, or is accompained by fever, rash, or persistent headache. These could be signs of a serius condition. \blacksquare sore mouth does not improve in 7 days \blacksquare irritation, pain, or redness persists or worsens.

Keep out of reach of children.

Directions

- adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor.

Other information

■ 10 calories per drop ■ contains: SOY.

Inactive ingredients

MENTHOL
ACESULFAME POTASSIUM
ASPARTAME
FD&C BLUE NO. 1
FD&C RED NO. 40
POTASSIUM CITRATE
SOY LECITHIN
CITRIC ACID
EUCALYPTUS OIL
SUCRALOSE
ISOMALT
MALTITOL
WATER

Call 2396311907 or visit our website: www.mgc.us

Package Label - Principal Display Panel



MGC HEALTH

cough drops menthol sugar-free lozenge

| D | 1 £ +! |
|---------|-------------|
| Product | Information |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61658-113

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| ACESULFAME POTASSIUM (UNII: 230V73Q5G9) | |
| ISOMALT (UNII: S870P55O2W) | |
| EUCALYPTUS OIL (UNII: 2R040NI662) | |
| ASPARTAME (UNII: Z0H242BBR1) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

MALTITOL (UNII: D65DG142WK)

POTASSIUM CITRATE (UNII: EE900NI6FF)

Product Characteristics

| Color | blue | Score | score with uneven pieces |
|----------|---------|--------------|--------------------------|
| Shape | OVAL | Size | 21mm |
| Flavor | MENTHOL | Imprint Code | В |
| Contains | | | |

| Pa | cka | aain |
|----|-----|------|

| | rackaying | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | t Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:61658-113- 70 | 70 in 1 BAG; Type 0: Not a Combination Product | 02/12/2023 | |
| 2 | NDC:61658-113- 25 | 25 in 1 BAG; Type 0: Not a Combination Product | 02/12/2023 | |
| | | | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 02/12/2023 | |
| | | | |

Labeler - YUNNAN BAIYAO GROUP CO., LTD (654223122)

Revised: 5/2023 YUNNAN BAIYAO GROUP CO., LTD