BRONCO PULMONAR SYRUP- guaifenes in, dextromethrophan hbr liquid Menper Distributors, Inc.

| Disclaimer: Most OTC drugs are not reviewed and approved by FDA, h | nowever they may be marketed if they |
|------------------------------------------------------------------------|--------------------------------------|
| comply with applicable regulations and policies. FDA has not evaluated | l whether this product complies. |

Active ingredients (in each 5mL tsp)

Expectorant

Cough Suppressant

Uses

• Temporarily relieves cough due to minor throat and bronchial irritation and nasal congestion as may occur with the common cold or inhaled irritants

Warnings Do not exceed recommended dosage.

• A persistent cough may be a sign of a serious condition. If cough persists more than one week, tends to reoccur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

Do not use:

- This product for persistent or chronic cough, such as occurs with smoking, asthma, or emphysema or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Keep out of reach of children.

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

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

Directions

• Do not exceed 6 doses in 24 hours.

age dose

Adults and children 2 teaspoonfuls (10 mL)

12 years of age and over...... every 4 hours

Children 6 to under 1 teaspoonful (5 mL)

12 years of age.... every 4 hours

Children 2 to under 1/2 teaspoonful (2.5 mL)

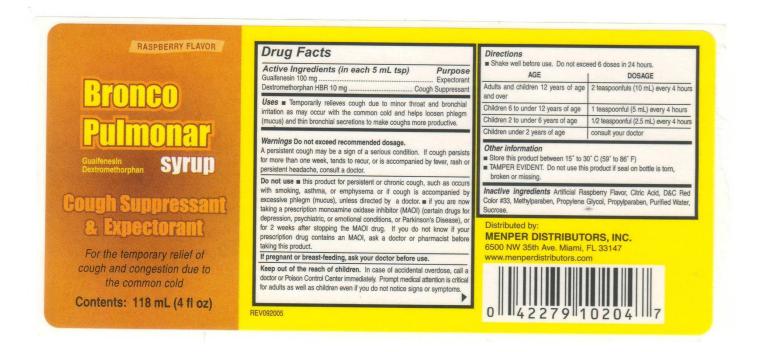
6 years of age...... every 4 hours

Children under 2 years of age...... consult your doctor

Other information

- Store this product between 15°-30°C (59°-86°F)
- TAMPER EVIDENT. Do not use this product if seal on bottle is torn, broken or missing.

Inactive ingredients Artificial Raspberry Flavor, Citric Acid, D&C red #33, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Sucrose



BRONCO PULMONAR SYRUP

guaifenesin, dextromethrophan hbr liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53145-030 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|------------------------------------------------------------------------------------------------|----------------------------------|-------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 5 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------------|----------|
| RASPBERRY (UNII: 4N14V5R27W) | |
| CITRIC ACID ACETATE (UNII: DSO 12WL7AU) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| METHYLPARABEN (UNII: A2I8 C7HI9 T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8 IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| SUCROSE (UNII: C151H8 M554) | |

| P | Packaging | | | |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:53145-030-04 | 1 in 1 CARTON | | |
| 1 | | 120 mL in 1 BOTTLE | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 0 2/2 1/2 0 12 | |
| | | | |

Labeler - Menper Distributors, Inc. (101947166)

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