

BRONCOTRON - dextromethorphan, guaifenesin liquid
Seyer Pharmatec, Inc.

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.

Drug Facts

Active ingredients (in each 5 mL teaspoonful) Purpose

Dextromethorphan HBR, 10 mg.....Cough suppressant
Guaifenesin, 100 mg..... Expectorant

Uses:

- temporarily relieves cough due to minor throat and bronchial irritations as may occur with a cold.
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings:

Ask a doctor before use if you have:

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, bronchitis, or emphysema.

Stop use and ask a doctor if:

- Cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

Do not use if you are now taking a prescription monoamine oxidase (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 the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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

Directions

- **do not take more than 6 doses in any 24-hour period, unless directed by a physician.**

| Age | Doses |
|---------------------------------------|------------------------------|
| adults and children 12 years and over | 2 teaspoonfuls every 4 hours |
| children 6 years to under 12 years | 1 teaspoonful every 4 hours |
| children under 6 years | ask a doctor |

Other information:

- Phenylketonuric: contains Phenylalanine 35mg/5mL
- store at room temperature.

Inactive ingredients:

Aspartame, citric acid, flavor, glycerine, hydroxyethyl cellulose, methylparaben, propylparaben, sodium citrate, water.

Questions or Comments call: 1(800) 782- 3585.

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Other information
 ■ Phenylephrine: contains Phenylephrine 12.5mg/5mL
 ■ store at room temperature
 ■ questions or comments Call 1 (888) 782-3585

Inactive ingredients
 aspartame, citric acid, flavor, glycerine, hydroxyethyl cellulose, methylparaben, propylparaben, sodium citrate, water.

Tamper-Evident Disclosure: Do not use this product if printed foil under cap is torn, broken or missing.
 Code#SEY264-04 Rev. 03/10
 Lot# / Exp. Date:
 Manufactured in the USA for:
SEYER
 PHARMATEC INC.
 Sanyalabs, Puerto Rico 00970

BRONCOTRON

dextromethorphan, guaifenesin liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11026-2640 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|-------------------|
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 5 mL |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ASPARTAME (UNII: Z0H242BBR1) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| POLYGLYCERIN-10 (UNII: P9060O936A) | |
| HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| WATER (UNII: 059QF0K00R) | |

Product Characteristics

| | | | |
|-----------------|------------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHERRY (Cherry Flavor) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:11026-2640-4 | 118 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 01/01/1998 | |

Labeler - Seyer Pharmatec, Inc. (832947126)**Registrant** - Seyer Pharmatec, Inc. (832947126)

Revised: 12/2011

Seyer Pharmatec, Inc.