

BRONCOMAR- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Gadal Laboratories 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.

| Active ingredients: (in 10 ml) | Purpose |
|---------------------------------------|-------------------|
| Acetaminophen 200 mg | Analgesic |
| Dextromethorphan HBr 13.33 mg | Cough Suppressant |
| Guaifenesin 200 mg | Expectorant |
| Phenylephrine HCl 5 mg | Decongestant |

Purpose

- Analgesic
- Cough Suppressant
- Expectorant
- Decongestant

Uses

- □For temporary relief of bronchial and nasal congestion
- □Help loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

Do not exceed recommended dosage

Liver warning: □This product contains Acetaminophen. Severe liver damage may occur if

- Adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- Child takes more than 5 doses in 24 hours
- Taken with other drugs containing Acetaminophen
- Adult has 3 or more alcoholic drinks everyday while using this product
- Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician

Do not use

- If you are now taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression, psychiatric conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug.
- if you do not know if your prescription drug contains on MAOI ask your doctor or pharmacist before taking this product
- if you have a chronic pulmonary disease or shortness of breath unless directed by a doctor
- avoid alcoholic beverages while you are taking this product
- do not use with any other drug containing Acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains Acetaminophen, ask a doctor or a pharmacist.

Ask the 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, chronic bronchitis or emphysema
- heart disease, high blood pressure, thyroid disease, or difficulty in urination due to the enlargement of prostate gland.
- The user has liver disease
- The user is taking the blood thinning drug Warfarin.

☐ Stop use and ask the doctor if

- ☐ Nervousness, dizziness or sleeplessness occurs.
- Cough persists for more than 1 week, tends to recur, or accompanied by fever, rash or persistent headache. A persistent cough may be sign of a serious condition

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

☐ Keep out of reach of children. ☐ In case of overdose, get medical help or contact a Poison Control Center right away.

☐ Directions

- ☐ Do not take more than 6 doses in any 24-hour period

☐ Age

Dose

☐ Adults and children 12 years and over 10 mL (2 tsps) every 6 hours

Children 6 to under 12 years of age. 5 mL (1 tsps) every 6 hours

☐ Children under 6 years of age

Do not use

☐ Inactive ingredients

Aloe vera, citric acid, disodium EDTA, FD&C Red #40, hydroxyethyl cellulose, natural strawberry flavor, propylene glycol, water, sodium benzoate, sorbitol 70%, sucralose

Great Strawberry Flavor
EXPECTORANT

Broncomar

NEW FORMULA

Broncomar

EXPECTORANT
Cough Suppressant · Descongestant · Analgesic
ACETAMINOPHEN
Great Strawberry Flavor

Alcohol & Sugar Free
PARABEN FREE

Relieves Bronchial Congestion & Loosens Mucus

ALOE VERA  **SYRUP**

Net Wt. 6 fl. Oz. (177 mL)

Drug Facts

Active ingredients: (in 10 ml)..... Purpose
 Acetaminophen 250 mg..... Analgesic
 Dextromethorphan Hbr 13.33 mg.....Cough Suppressant
 Guaifenesin USP 200mg..... Expectorant
 Phenylephrine HCL 5mg..... Decongestant

Uses

- For temporary relief of Bronchial and Nasal Congestion
- Help loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.
- Temporarily relieves cough due the minor throat and bronchial irritation as may occur with the common cold.

Warnings

Do not exceed recommended dosage.
Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if

- Adult takes more than 6 doses in 24 hours, which is the maximum daily amount.
- Child takes more than 5 doses in 24 hours.
- Taken with other drugs containing Acetaminophen.
- Adult has 3 or more alcoholic drinks everyday while using this product.
- Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician

Do not use

- If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression , psychiatric 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 your doctor or pharmacist before taking this product.
- If you have a chronic pulmonary disease or shortness of breath unless directed by a doctor.
- Avoid alcoholic beverages while you taking this product.
- Do not use with any other drug containing Acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains Acetaminophen, ask a doctor or a pharmacist.

Ask the doctor before use if or you have

- Cough that occurs with too much phlegm (mucus)
- Cough that last or is a chronic such as occurs with smoking , asthma , chronic bronchitis or emphysema.
- Heart disease, high blood pressure, thyroid disease, or difficulty in urination due enlargement of prostate gland.
- The user has Liver disease
- The user is taking the blood thinning drug Warfarin.

Stop use and ask the doctor if

- Nervousness, dizziness or sleeplessness occurs.
- Cough persists for more than 1 week, tends to recur, or accompanied by fever, rash or persistent headache. A persistent cough may be sign serious condition

NUEVA FORMULA

Broncomar

EXPECTORANTE
Antitussivo · Descongestionante · Analgesico
ACETAMINOFÉN
Agradable Sabor a Fresa

Sin Alcohol & Sin Azúcar
LIBRE DE PARABENOS

Alivia la Congestión Bronquial & Afloja la Flema y la Mucosidad

ALOE VERA  **JARABE**

PESO NETO 6 fl. Oz. (177 mL)

Continued

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Si esta embarazada o en periodo de lactancia. Consulte con un profesional de la salud antes de usar este producto. **Mantenga fuera del alcance de los niños,** en caso de sobredosis obtenga ayuda medica o póngase en contacto con un centro de envenenamiento inmediatamente.

Directions:

- Do not take more than 6 doses in any 24-hour period.

| Age | Dose |
|---------------------------------------|----------------------------|
| Adults and Children 12 years and over | 10ml (2 tsp) every 6 hours |
| Children 6 to under 12 years of age. | 5ml (1 tsp) every 6 hours |
| Children under 6 years of age | Do not use |

Instrucciones :

- No tome mas de 6 dosis en un periodo de 24 horas.

| Edad | Dosis |
|------------------------------------|-----------------------------|
| Adultos y niños mayores de 12 años | 10ml (2 Ctas.) cada 6 horas |
| Niños de 6 hasta 12 años | 5ml (1 Cfta.) cada 6 horas |
| Niños menores de 6 años de edad | No Utilice este producto |

Other Information

- Each 10 ml contains: sodium 2 mg
- Store Between 15-30° C (59-86° F)
- Tamper Evident Feature Do not use if seal under cap is tom, broken or missing

Inactive Ingredients
 Aloe Vera , Citric Acid, Disodium EDTA, FD&C Red # 40, Hydroxyethyl Cellulose, Natural Strawberry Flavor , Propylene Glycol USP, Purified Water, Sodium Benzoate, Sorbitol 70% USP, Sucralose.

Ingredientes inactivos
 Aloe Vera, Acido Citrico, Sucrolosa, Hidroxietyl Celulosa , EDTA Disodico, Benzonato Sodico, Propilen Glycol USP, Color Rojo FD &C # 40, Sabor Fresa natural , Agua Purificada, Sorbitol 70% USP.

Questions or Comments?
 Call Weekdays from 9:30 AM to 5 PM EST at Tel. 305 2618762

Preguntas o Comentarios? Llamar de 9:30 AM a 5 PM tiempo este , en días laborables TEL. 305 32618762.

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 Made In U.S.A.



NDC 53113-215-06

BRONCOMAR

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

| | | | | |
|--|---|----------------------------------|-----------------------------|---------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53113-215 | |
| Route of Administration | ORAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | | ACETAMINOPHEN | 250 mg in 10 mL | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | | DEXTROMETHORPHAN HYDROBROMIDE | 13.33 mg in 10 mL | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | | GUAIFENESIN | 200 mg in 10 mL | |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 10 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| ALOE VERA WHOLE (UNII: KIZ4X2EHYX) | | | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | | |
| HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:53113-215-06 | 1 in 1 CARTON | | |
| 1 | | 177 mL in 1 BOTTLE | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part341 | 06/01/2014 | | |

Labeler - Gadal Laboratories Inc (841305639)