

**BRONCOMAR EXPECTORANT- acetaminofen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid**

**Dannso Corp./d.b.a. Essential Products**

*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.*

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**Broncomar Expectorant**

| Active Ingredients:(in each 10 ml.)          | Purpose           |
|----------------------------------------------|-------------------|
| Acetaminophen 250 mg .....                   | Analgesic         |
| Dextromethorphan Hydrobromide 13.33 mg ..... | Cough Suppressant |
| Guaifenesin USP 200 mg.....                  | Expectorant       |
| Phenylephrine HCl 5 mg.....                  | Decongestant      |

**Uses:**

- For temporary relief of Bronchial and Nasal congestion
- Helps 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 every day 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 MAOI drug.
- If you do not know if your prescription drug contains MAOI as 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 beverage while 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 pharmacist

**Stop use and ask a doctor**

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

**Ask doctor before use if 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 diseases
- The user us taking the blood thinning drug Warfarin

**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 exceed 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 tsp) every 6 hours   |
| Children under 6 years of age         | Do not use                   |

**Other Information:**

- Each 10 mls contains: sodium 4 mg
- Store between 15 - 30 degrees Celsius (59 - 86 Fahrenheit).
- Tamper Evident Feature:Do not use if seal under cap is torn, broken or missing.

**Inactive Ingredient**

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

**Questions or Comments**

Call Weekdays from 9:30 AM to 5PM EST at Tel 305-261-762

**Distributed by**

**Essential Products Miami FL 33126**

[www.jjjdistributors.com](http://www.jjjdistributors.com)

**Made in U.S.A.**

**Drug Facts**

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 Dextromethorphan HBr 13.33 mg.....Cough Suppressant  
 Guaifenesin USP 200mg.....Expectorant  
 Phenylephrine HCL 5mg.....Decongestant

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 ■ Helps 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**  
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 ■ 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 every day 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.

# Broncomar®

## EXPECTORANT

Cough Suppressant · Decongestant · 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)

■ 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.

**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 | 10ml (2 tsp) every 6 hours |
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**Other information**  
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 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.

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

Distributed by **essentialProducts** Miami, FL 33126  
[www.jjistributors.com](http://www.jjistributors.com)  
 Made in U.S.A.

Lot #.  
Exp. Date.

## BRONCOMAR EXPECTORANT

acetaminofen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70 242-102 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name                                                                       | Basis of Strength                | Strength             |
|---------------------------------------------------------------------------------------|----------------------------------|----------------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                    | ACETAMINOPHEN                    | 250 mg<br>in 10 mL   |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 13.33 mg<br>in 10 mL |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                        | GUAIFENESIN                      | 200 mg<br>in 10 mL   |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)      | PHENYLEPHRINE<br>HYDROCHLORIDE   | 5 mg<br>in 10 mL     |

### Inactive Ingredients

| Ingredient Name                                            | Strength |
|------------------------------------------------------------|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                          |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)                 |          |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                        |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                         |          |
| HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP) |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                        |          |
| WATER (UNII: 059QF0K00R)                                   |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                         |          |
| SORBITOL (UNII: 506T60A25R)                                |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                               |          |

**Packaging**

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:70242-102-06 | 1 in 1 CARTON                                         | 01/01/2015           |                    |
| 1 |                  | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part341                                  | 10/01/2001           |                    |

**Labeler** - Danso Corp./d.b.a. Essential Products (059741071)

**Registrant** - Danso Corp./d.b.a. Essential Products (059741071)

**Establishment**

| Name           | Address | ID/FEI    | Business Operations    |
|----------------|---------|-----------|------------------------|
| All Pharma LLC |         | 078572520 | MANUFACTURE(70242-102) |

Revised: 1/2016

Danso Corp./d.b.a. Essential Products