

CONEX- dexbrompheniramine maleate, pseudoephedrine liquid
Llorens Pharmaceutical International Division

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 tsp.)

Dexbrompheniramine Maleate, USP 1 mg Antihistamine

Pseudoephedrine HCL, USP 30 mg Nasal Decongestant

Uses:

- Temporarily relieves nasal congestion due to common cold, hay fever or other upper respiratory allergies
- Helps decongest sinus openings and sinus passages
- Reduces swelling of nasal passages, shrinks swollen membranes, and temporarily restores freer breathing through the nose
- Temporarily alleviates the following symptoms due to hay fever (allergic rhinitis): runny nose, sneezing, itching of the nose or throat, itchy and watery eyes.

Warnings:

- **Do not use if** you are 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 you are taking a prescription drug that contains an MAOI, ask your doctor or pharmacist before taking this product.

Ask a doctor before use if you are taking sedatives or tranquilizers.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- difficulty in urination due to the enlargement of the prostate gland.

When using this product

- do not exceed the recommended dosage
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever.

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 Professional before use.

Directions: Do not exceed more than 4 doses in any 24-hour period or as directed by a doctor.

| Age | Dose |
|--|--|
| Adults and children 12 years of age and over | take two teaspoonfuls (10 mL) every 4 to 6 hours |
| Children 6 to under 12 years of age | take one teaspoonful (5 mL) every 4 to 6 hours |
| Children under 6 years of age | ask a doctor |

Other Information:

- Store at controlled room temperature 20-25 degree celcius (68-77 degree farenheit); excursions permitted to 15-30 degree clecius (59-86 degree farenheit) (See USP Controlled Room Temperture) Tamper evident by imprinted heat seal under cap
- Do not use if there is evidence of tampering
- **WARNING: Phenylketonuric: Contains 13.5 mg of Phenylalanine per 5 mL (one teaspoonful) dose.**

Inactive Ingredients: aspartame, cherry flavor, citric acid, glycerine, menthol, methylparaben, potassium citrate, potassium sorbate, propylene glycol, propylparaben and purified water.

Questions or Comments? 1-866-595-5598

NDC 54859-802-04

Drug Facts

Active ingredients (in each 5 mL tsp.) Purpose
Dexbrompheniramine Maleate, USP..... 1 mg..... Antihistamine
Pseudoephedrine HCl, USP..... 30 mg.... Nasal Decongestant

Uses ■ Temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies ■ helps decongest sinus openings and sinus passages ■ reduces swelling of nasal passages, shrinks swollen membranes, and temporarily restores freer breathing through the nose ■ temporarily alleviates the following symptoms due to hay fever (allergic rhinitis) ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy and watery eyes

Warnings ■ **Do not use** if you are 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 you are taking a prescription drug that contains an MAOI, ask your doctor or pharmacist before taking this product.

Ask a doctor before use if you are taking sedatives or tranquilizers.

Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ difficulty in urination due to the enlargement of the prostate gland.

When using this product ■ do not exceed the recommended dosage ■ excitability may occur, especially in children ■ drowsiness may occur ■ avoid alcoholic beverages ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if ■ nervousness, dizziness or sleeplessness occur ■ symptoms do not improve within 7 days or occur with a fever.

Rev

Oral Solution

- Nasal & Sinus Congestion
- Runny Nose, Sneezing
- Itchy, Watery Eyes

• ANTIHISTAMINE

• NASAL DECONGESTANT

4 FL OZ (118 mL)

www.llorenspharm.com

MANUFACTURED FOR
LLORENS
PHARMACEUTICAL CORP
International Division
Miami, FL 33146

Drug Facts (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.

Directions Do not exceed more than 4 doses in any 24-hour period or as directed by a doctor.

| Age | Dose |
|--|--|
| Adults and children 12 years of age and over | take two teaspoonfuls (10 mL) every 4 to 6 hours |
| Children 6 to under 12 years of age | take one teaspoonful (5 mL) every 4 to 6 hours |
| Children under 6 years of age | ask a doctor |

Other information ■ Store at controlled room temperature 20° - 25° C (68° - 77° F); excursions permitted to 15-30° C (59-86°F) (See USP Controlled Room Temperature) Tamper evident by imprinted heat seal under cap ■ Do not use if there is evidence of tampering ■ **WARNING: Phenylketonuric: Contains 13.5 mg of Phenylalanine per 5 mL (one teaspoonful) dose.**

Inactive Ingredients: aspartame, cherry flavor, citric acid, glycerine, menthol, methylparaben, potassium citrate, potassium sorbate, propylene glycol, propylparaben and purified water.

Questions or Comments? 1-866-595-5598

Distributed By: Llorens International Division, Miami FL 33188

Lot, #

Exp. Date:

CONEX

dexbrompheniramine maleate, pseudoephedrine liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54859-802 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|------------------|
| DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP) | DEXBROMPHENIRAMINE MALEATE | 1 mg in 5 mL |
| PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 30 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ASPARTAME (UNII: Z0H242BBR1) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| POTASSIUM CITRATE (UNII: EE90ONI6FF) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |

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:54859-802-04 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2007 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 11/01/2007 | |

Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2020

Llorens Pharmaceutical International Division