

CONEX- dexbrompheniramine maleate, pseudoephedrine hcl tablet
LLORENS PHARMACEUTICALS 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 film coated tablet)	Purpose
Dexbrompheniramine Maleate, USP 2 mg	Antihistamine
Pseudeophedrine HCl, USP 60 mg	Nasal Decogestant

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, itching and watery eyes.

Warnings:

Ask a doctor before you use if you are

- taking sedatives or tranquilizers.

Ask your 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 doctor if

- nervousness, dizziness or sleepiness occur
- symptoms do not improve withing 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.

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 MAOI;

ask your doctor or pharmacist before taking this product.

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

Adults and children 12 years of age and over	Take one tablet every 4 to 6 hours
Children 6 to under 12 years of age	1/2 tablet every 4 to 6 hours
Children under 6 years of age	Ask a doctor

Other Information: Store at controlled room temperature 20 - 25 degree celsius (68 - 77 degree fahrenheit); excursions permitted to

15 - 30 degree celsius (59 - 86 degree fahrenheit) [See USP Controlled Room Temperature] Tamper evident by imprinted heat seal

under cap. Do not use if there is evidence of tampering.

Inactive Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Magnesium Stearate, Sodium Starch Glycolate type B, Purified Water, Red iron Oxide, Yellow Iron Oxide, Titanium Dioxide.

Questions or Comments?

1-866-595-5598

CONEX

dexbrompheniramine maleate, pseudoephedrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-702
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
WATER (UNII: 059QF0KO0R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	LLORENS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-702-60	60 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 PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)**Registrant** - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)