

TUSNEL DM- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Llorens Pharmaceutical International Division, 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.

In each 5 mL

Dextromethorphan HBr - 20 mg

Guaifenesin - 400 mg

Phenylephrine HCl - 10 mg

Purpose

□Cough Suppressant

Expectorant

Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold
- nasal congestion •cough due to minor throat and bronchial irritation

Warnings

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

□Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of prostate gland
- a cough with too much phlegm (mucus)
- a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema
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Stop use and ask a doctor if you get

- nervousness, dizziness, or sleeplessness occur
- cough lasts for more than 7 days, comes back or occurs with a fever, rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a doctor before using this product

Keep out of reach of children. In case of accidental overdose, seek advice of a doctor or contact a Poison Control Center right away.

Directions: Do not exceed 6 doses in 24 hour

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-517-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2019	

Labeler - Llorens Pharmaceutical International Division, Inc. (037342305)

Registrant - Llorens Pharmaceutical International Division, Inc. (037342305)

Establishment

Name	Address	ID/FEI	Business Operations
Llorens Pharmaceutical International Division, Inc.		037342305	manufacture(54859-517)

Revised: 6/2019

Llorens Pharmaceutical International Division, Inc.