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 [lif 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 enlargment 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

Age Adults and children over 12 years of age Children under 12 years of age Dose
Take 5 mL (one teaspoonful) every 4 hours
Ask a doctor

Inactive ingredients: artificial and natural flavor, citric acid, glycerin, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose

Questions or Comments? 1-866-595-5598



TUSNEL DM

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-517
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 5 mL
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength

ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

1 ackaging			
# 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 Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

05/01/2019

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

part341

Packaging

OTC monograph final

$\pmb{Registrant - \text{Llorens Pharmaceutical International Division, Inc. (037342305)}}$

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

Revised: 6/2019 Llorens Pharmaceutical International Division, Inc.