HISTEX-DM- dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride syrup
Allegis Pharmaceuticals, LLC

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.

HISTEX™-DM Syrup

Drug Facts

Active ingredients (in each 5 mL teaspoonful)	***Purpose***
Dextromethorphan HBr 20 mg	Cough Suppressant
Phenylephrine HCl 10 mg	Decongestant
Triprolidine HCl 2.5 mg	Antihistamine

Uses

temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat or bronchial irritation
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

- If you are now 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a persistent or chronic cough such occurs with smoking, asthma, chronic bronchitits, or emphysema
- a cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland

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

When using this product

- excitability may occur, especially in children
- may cause drowsiness
- alcohol, sedatives and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not exceed recommended dosage.

AGE	**DOSE**
Adults and Children 12 years of age and older:	1 teaspoonful (5 mL) every 4 hours, not to exceed 4 teaspoonfuls (20 mL) in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age	½ teaspoonful (2.5 mL) every 4 hours, not to exceed 2 teaspoonfuls (10 mL) in 24 hours, or as directed by a doctor.
Children under 6 years of age	Consult a doctor

Other Information

Store at 15°-30° C (59°-86° F).

Tamper evident by foil seal under cap. Do not use if foil seal is missing or broken.

Dispense in a tight, light-resistant container with a child-resistant cap.

Inactive ingredients

Citric Acid, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol, Grape Flavor.

Questions? Comments?

Call 1-866-633-9033.

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 28595-804-16

Antihistamine • Decongestant
Cough Suppressant

HISTEX™-DM
Syrup

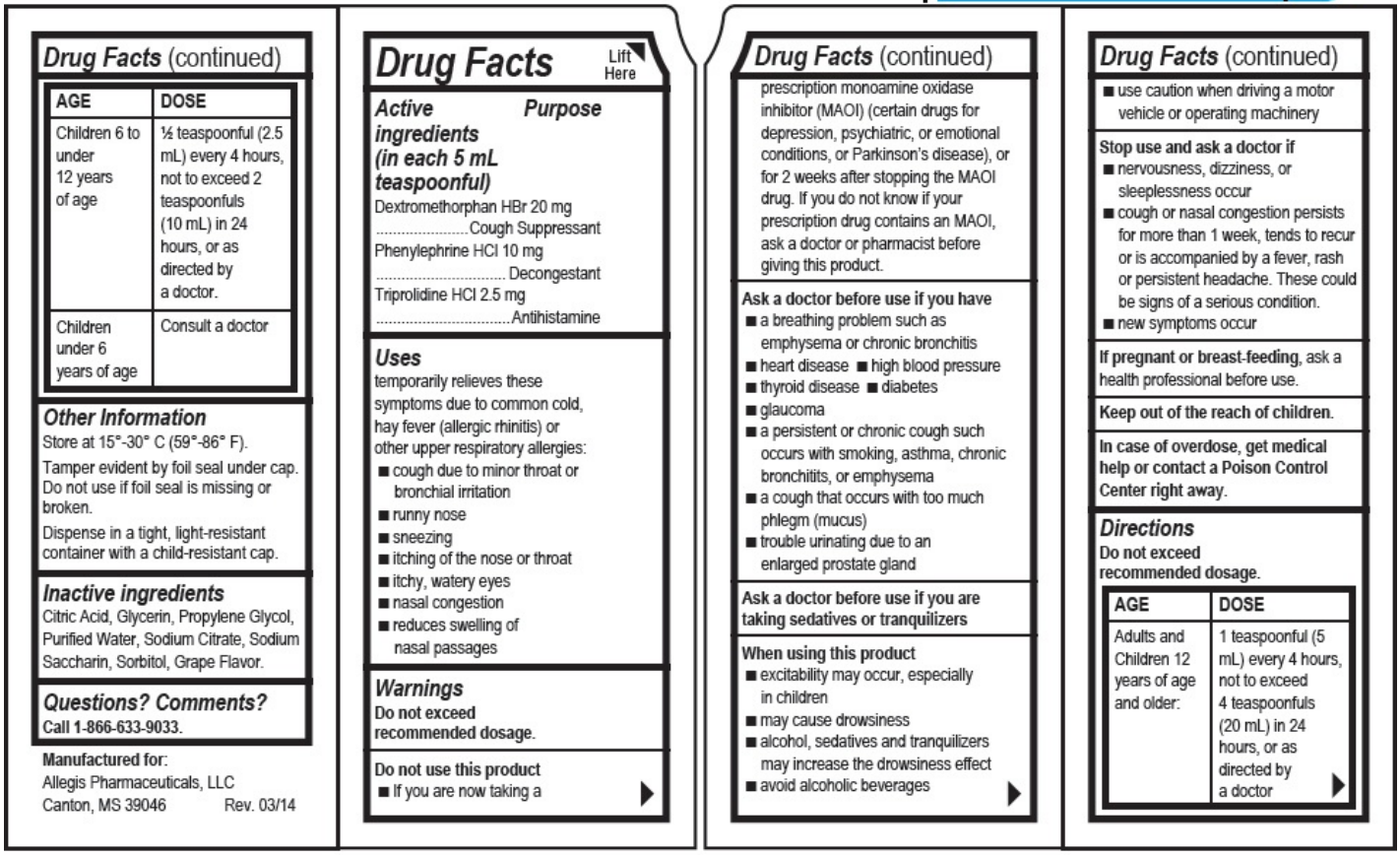
Each teaspoonful (5 mL)
contains:

Dextromethorphan HBr	20 mg
Phenylephrine HCl	10 mg
Triprolidine HCl	2.5 mg

Sugar-Free • Dye Free
Alcohol Free

Grape Flavor

16 fl oz (473 mL)



HISTEX-DM

dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride syrup

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:28595-804
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:28595-804-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/19/2014	

Labeler - Allegis Pharmaceuticals, LLC (792272861)

Revised: 3/2014 Allegis Pharmaceuticals, LLC