# TUSSLIN TR- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet KRAMER NOVIS

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.

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#### **DRUG FACTS**

Active Ingredients(in each tablet): Guaifenesin 388 mg, dextromethorphan hydrobromide 28 mg, phenylephrine hydrochloride 10 mg

Cough Suppressant, Expectorant, Nasal Decongestant

Uses • temporarily relieves cough due to minor throat or bronchial irritation associated with a cold or inhaled irritants • helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive • temporarily relieves nasal congestion due to a cold, hay fever or other respiratory allergies, reduces swelling of nasal passages; shrinks swollen membranes

Warning • 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before if you have • diabetes • heart disease • Thyroid disease • high blood pressure • trouble urinating due to an enlarged prostate gland • cough that occurs with too much phlegm (mucus) • cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

When using this product do not use more than directed.

Stop use and ask a doctor if • nervousness, dizziness or sleeplessness occur • symptoms do not get better within 7 days or are accompanied by fever • coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or a persistent headache. These could be signs of a serious condition.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

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

Inactive ingredients

Hypromellose Maltodextrin, Microcrystalline Cellulose, Polyethylene Glycol / Macrogol, Povidone, Sodium Starch Glycolate, Stearic Acid

Directions • do not exceed recommended doses in a 24 hour period.

- Adults and Children 12 years of age and over. 1 tablet every 6-8 hours. Do not exceed 4 tablets in 24 hours.
- Children 6 to under 12 years of age: 1/2 tablet every 6-8 hours. Do not exceed 2 tablets in 24 hours.
- Children under 6 years of age: ask physician.

#### **Packaging**

Lot **Drug Facts** 

Active Ingredients (in each tablet) Purpose Dextromethorphan HBr, 28 mg. Cough Suppressant Guaifenesin, 388 mg. .Expectorant Phenylephrine HCI, 10 mg. .Nasal Decongestant

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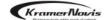
NDC 52083-617-10

### Contains the same active ingredients as Giltuss® TR\*

Dextromethorphan HBr. Guaifenesin .. 388 ma Phenylephrine HCI . . 10 mg

### ANTITUSSIVE **EXPECTORANT** NASAL DECONGESTANT

SUGAR AND PRESERVATIVE FREE 100 Tablets



Drug Facts (continued)

Stop use and ask a doctor if • nervousness, dizziness or sleeplessness occur • symptoms do not get better within 7 days or are accompanied by fever • coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or a persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions - do not exceed recommended doses in a 24 hour period.

• Adults and Children 12 years of age and over. 1 tablet every 6-8 hours. Do not exceed 4 tablets in 24 hours.

• Children 6 to under 12 years of age: ½ tablet every 6-8 hours. Do not exceed 2 tablets in 24 hours.

• Children under 6 years of age: ask physician.

Other information • Tamper evident feature: Do not use if inner seal is torn, broken or missing. • Store at controlled room temperature 15-30°C (59-86°F) • Avoid excessive heat or humidity.

Inactive ingredients hypromellose maltodextrin, microcrystalline cellulose, polyethylene glycol / macrogol, povidone, sodium starch glycolate, silicon dioxide, stearic acid

Manufactured in the USA for Kramer Novis. San Juan, PR 00917 Tel: (787) 767-2072 / www.kramernovis.com

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#### TUSSLIN TR

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52083-617

**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength DEXTROMETHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) **DEXTROMETHORPHAN** 28 (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) **GUAIFENES IN** 388 PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 10 UNII:1WS297W6MV) HYDROCHLORIDE

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)				
PO VIDO NE (UNII: FZ989GH94E)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
STEARIC ACID (UNII: 4ELV7Z65AP)				

Product Characteristics					
Color	white	Score	2 pieces		
Shape	OVAL	Size	17mm		
Flavor		Imprint Code	tr		
Contains					

Start Date M	
Start Date Ma	larketing End Date

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	05/04/2015				

## Labeler - KRAMER NO VIS (090158395)

## **Registrant -** KRAMER NO VIS (090158395)

Revised: 12/2017 KRAMER NOVIS