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.

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

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**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	28
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	388
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POVIDONE (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			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-617-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2015	

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

Labeler - KRAMER NOVIS (090158395)

Registrant - KRAMER NOVIS (090158395)

Revised: 12/2017 KRAMER NOVIS