TEXACLEAR KIDS COUGH AND COLD- dextromethorphan hbr guaifenesin phenyephrine hcl liquid GM Pharmaceuticals, INC

TexaClear Kids Daytime cough and cold

TexaClear® Kids Daytime Cough & Cold (dextromethorphan hbr, guaifenesin, phenylephrine hcl), solution GM Pharmaceuticals, Inc.

Drug Facts

Active ingredients (in each 30 mL)

Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

Purpose

Cough suppressant Expectorant Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.
- temporarily relieves:
- the intensity of coughing
- nasal congestion due to a cold
- stuffy nose
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants

Warnings

Do not exceed recommended dosage.

Do not use

- 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 taking this product.
- in children under 6 years of age

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking any other oral nasal decongestant or stimulant

When using this product

do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days, or are accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- do not exceed 6 doses per 24-hour period
- use enclosed (30 mL) dose cup \blacksquare mL = milliliter
- dose every 4 hours
- adults and children 12 years and over:60 mL (2 dose cups)
- children 6 to under 12 years: 30 mL (1 dose cup)
- children under 6 years: do not use

Other information

- each 30 mL contains: Sodium 15 mg
- read all product information before using
- store at room temperature 68-86°F (20-30°C)

Inactive ingredients

citric acid, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, sucralose

Questions or comments?

Call 1-888-535-0305 9 a.m. - 5 p.m. CST.

Distributed by:

GM Pharmaceuticals, Inc. Arlington, TX. 76015

Principal Display Panel

TexaClear® Kids Daytime Cough & Cold

NDC 58809-950-08

8 fl. oz. (237 mL)

Dextromethorphan HBR - Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCL - Nasal Decongestant

Tamper evident: do not use if foil seal under cap is broken on missing

- Gluten Free
- Dye Free
- Sugar Free
- Alcohol Free
- Acetaminophen Free

Ages 6+

Relieves:

- Nasal & Chest Congestion
- Thins & Loosens Mucus
- Cough

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-950
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 30 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 30 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 30 mL		

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6A3C0OX)		
MALTITOL (UNII: D65DG142WK)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2015	12/31/2024

Marketing In			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/15/2015	12/31/2024

Labeler - GM Pharmaceuticals, INC (793000860)