

**CHILDRENS TUSSNEX- acetaminophen, dextromethorphan hbr, guaifenesin,
phenylephrine hcl liquid
Guardian Drug Company**

Childrens Tussnex Multi-Symptom Cold and Fever

Active ingredients (in each 10 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- stuffy nose
- cough due to minor throat and minor bronchial irritation
- the intensity of coughing
- the impulse to cough to help your child get to sleep
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Warnings

- **Liver warning:** This product contains acetaminophen. severe liver damage may occur if your child takes
- more than 5 doses in 24 hours, which is maximum daily amount
- with other drugs containing acetaminophen
- **Sore throat warning:** if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

Do not use

- **with any other drug containing acetaminophen** (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- in a child who is 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 the child has

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if

you are taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or persistent headache. These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a poison control center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult dose**

- **do not take more than directed (see overdose warning)**
- **shake well before use**
- do not take more than 5 doses in any 24 hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- **Children 6 to under 12 years of age:** 10 mL in dosing cup provided
- **Children under 6 years of age:** Do not use

Other information

- **each 10 mL contains:** sodium 10 mg
- store between 15-30°C(59-86°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

citric acid anhydrous, edetate disodium, FD and C blue 1, FD and C red 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

PDP

Compare to the active ingredients in Mucinex Childrens Multi-symptom Cold and Fever

Childrens Tussnex Multi symptom Cold and Fever

Acetaminophen

Pain reliever / Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Guaifenesin

Expectorant

Phenylephrine HCl

Nasal Decongestant

Relieves Nasal and chest congestion

Thins and loosens mucus

Reduces fever

Soothes cough

Alcohol Free

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-622-03	1 in 1 CARTON	05/05/2012	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/05/2012	

Labeler - Guardian Drug Company (119210276)

Registrant - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	manufacture(53041-622)

Revised: 12/2024

Guardian Drug Company