CONRX SINUS- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet Eagle Distributors, Inc.

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.

ConRx Sinus

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325mg Guaifenesin 200mg Phenylephrine HCl 5mg

Purpose

Pain reliever/ fever reducer Expectorant Nasal decongestant

Uses

Uses For the temporary relief of: sinus congestion and pressure, headache, nasal congestion, minor aches and pains, helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive, temporarily relieves nasal congestion due to the common cold, and hay fever and other upper respiratory allergies.

Warnings

- **Liver warning**: This product contains acetaminophen. Severe liver damage may occur if you take: more than 8 tablets in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- If you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease

- diabetes
- trouble urinating due to an enlarged prostate gland
- a persistent 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 exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts for more than 7 days
- fever gets more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of serious conditions.

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

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Adults and Children 12 years and over	 Take 1-2 tablets every 4 hours as needed Do not taking more than 8 tablets in 24 hour
Children under 12 years of age	Consult a doctor

Other Information

- Do not use if pouch is torn or damaged.
- Store between 15-30°C (59-86°F). Avoid excessive heat and humidity.
- See side panel for lot number and expiration date.

Inactive ingredients

Colloidal silicon dioxide, Sodium Lauryl Sulphate, Edetaet disodium, dioctyl sodium sulphosuccinate, polyvinyl pyrollidone, gelatin, corn starch', magnesium Stearate, microcrystalline cellulose, polyethylene glycol 6000, Sodium Benzoate, Sodium Starch Glycolate, Stearic acid, Purified Talc, Titanium Dioxide.

Product manufactured for:

Eagle Distributors, Inc.

Los Angeles, CA 90011

PRINCIPAL DISPLAY PANEL - 50 Pouch Carton

NDC: 68737-226-10

Compare to the Active Ingredients in Tylenol® Sinus Congestion & Pain*

ConRx **SINUS**

SEVERE Headache & Nasal Congestion

Acetaminophen
 Guaifenesin
 Phenylephrine HCl
 Headache & Pain
 Chest Congestion
 Nasal Congestion

TO OPEN PUSH IN TAB AND PULL OUT

Compare to the Active Ingredients in Tylenol[®] Sinus Congestion & Pain*

50 Pouches of 2 Caplets Each





Compare to the Active Ingredients in Tylenol[®] Sinus Congestion & Pain^{*} SEVERE Headache & Nasal Congestion Phenylephrine HCl

DO NOT USE WITH OTHER **MEDICINES CONTAINING ACETAMINOPHEN**

Headache & Pain

Chest Congestion

Nasal Congestion

*This product is not manufactured or distributed by: McNeil Consumer Speciality Pharmaceuticals Division of McNeil PPC, Inc. Eagle Distributors,Inc., does not own the Tylenol® Sinus Congestion & Pair

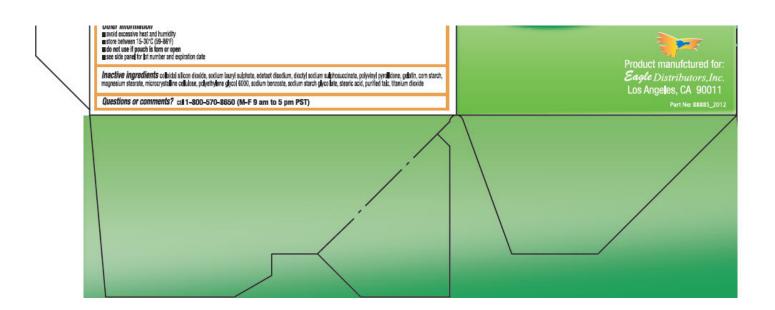
neadache nasal congestion minor aches and pains In this loces pringing (mucus) and thin bronchial secretions to make coughs more productive Itemporarily relieves nasal congestion due to the common cold, and hay lever and other upper respiratory allergies Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take mmore than 8 tablets in 24 hours, which is the maximum daily amount. ■with other drugs containing acetaminophen ■3 or more alcoholic drinks every day while using this product Do not use With any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist, will you are now taking a prescription montamine oxidase inhibitor (MAD) (certain drugs for decreasion, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MACI drug. If you do not know if your prescription drug contains an MACII ask a doctor or pharmacist before taking this product, will you have ever had an allergic reaction to this product or any of its ingredients. Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin When using this product do not exceed recommended dosage Stop use and ask a doctor if Stop use and ask a doctor if merousness, Stophen and ask a doctor if merousness, Stophens or cough gets worse or basts for more than 7 days in few gots worse or basts for more than 3 days in redness or swelling is present in mew symptoms occur in mew symptoms occur in cough comes have or occurs with rash or headache that lasts. 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. Overdose warming: In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. Directions

■ take 1-2 tablets every 4 hours as needed ■ do not take more than 8 tablets in 24 hours

m consult a doctor

adults and children 12 years and over

children under 12 years



CONRX SINUS

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68737-226
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Acetaminophen (UNII: 36209 ITL9D) (Acetaminophen - UNII: 36209 ITL9D)	Acetaminophen	325 mg		
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg		
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg		

Strength

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	ROUND	Size	12mm
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68737-226-10	50 in 1 BOX			
1		2 in 1 POUCH			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/11/2012	

Labeler - Eagle Distributors,Inc. (929837425)

Revised: 7/2012 Eagle Distributors,Inc.