# 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.

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ConRx<sup>TM</sup> 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	<ul> <li>Take 1-2 tablets every 4 hours as needed</li> <li>Do not taking more than 8 tablets in 24 hour</li> </ul>
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.

#### PRINCIPAL DISPLAY PANEL - 2 Caplets × 50 Pouch Box

**See New Warnings Information & Directions** 

# Compare to the Active Ingredients in

Tylenol® Sinus\*

Congestion & Pain\*

 $ConRx^{TM}$ 

SEVERE SINUS

# Headache & Nasal Congestion

- Acetaminophen Headache & Pain
- Guaifenesin Chest Congestion
- Phenylephrine HCl Nasal Congestion

# TO OPEN PUSH IN TAB AND PULL OUT

Compare to the Active Ingredients in

Tylenol<sup>®</sup> Sinus\*
Congestion & Pain\*

50 Pouches of 2 Caplets Each



**Headache & Nasal Congestion** 

- Acetaminophen
- Guaifenesin
- Phenylephrine HCl

Headache & Pain Chest Congestion Nasal Congestion

See New Warnings Information & Directions

Compare to the Active Ingredients in





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



# USO Pouches of 2 Caplets Each

- Chest Congestion Nasal Congestion Headache & Pain
- Phenylephrine HCI
  - Guaifenesin

# Headache & Nasai Congestion





Purposes
Pain reliever

Expectorant Nasal decongestant

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Compare to the Active Ingredients in See New Warnings Information & Directions

#### Drug Facts

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See New Warnings Information & Directions

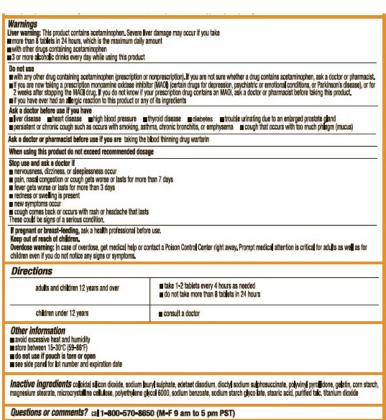
Compare to the Active Ingredients in

Congestion & Pain\*











#### **CONRX SINUS**

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68737-236
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		

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
BIS(1-METHYLAMYL) SODIUM SULFOSUCCINATE (UNII: 772Y8KZU65)			
STARCH, CORN (UNII: O8232NY3SJ)			
POVIDONE K90 (UNII: RDH86HJV5Z)			
GELATIN (UNII: 2G86QN327L)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30 IQX730 WE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	OVAL	Size	18 mm
Flavor		Imprint Code	CRX
Contains			

]	Packaging						
#	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date			
1	NDC:68737-236-20	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	02/15/2013	

# **Labeler** - Eagle Distributors,Inc. (929837425)

Revised: 2/2013 Eagle Distributors,Inc.