

CONRX COLD- acetaminophen, dextromethorphan hydrobromide, 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™ Cold

Drug Facts

<i>Active ingredients(in each caplet)</i>	<i>Purposes</i>
Acetaminophen 325 mg	Pain reliever
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- for the temporary relief of the following cold symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - cough
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets 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.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

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
- 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 exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 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 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 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. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• do not take more than directed (see overdose warning)

adults and children 12 years and over

- take 2 caplets every 4 hours
- swallow whole - do not crush, chew or dissolve
- do not take more than 12 caplets in 24 hours

children under 12 years

- do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- each caplet contains: **sodium 3 mg**
- store between 20-25°C (68-77°F)
- **do not use if card or pouch is torn or open**
- see side panel for lot number and expiration date

Inactive ingredients

carnauba wax, croscarmellose sodium, D&C yellow #10 aluminum lake, flavor, hydroxypropyl

cellulose, hypromellose, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, shellac, sucralose, titanium dioxide

Questions or comments?

1-800-570-8650

PRINCIPAL DISPLAY PANEL - 50 Pouch Box

See New Warnings Information & Directions

Compare to the Active Ingredients in

***Tylenol® Cold*
Head Congestion***

***ConRx™
SEVERE
COLD***

Sore throat - Cough - Headache - Nasal Congestant

TO OPEN

PUSH IN TAB AND PULL OUT

Compare to the Active Ingredients in

Tylenol® Cold* Head Congestion

50 Pouches of 2 Caplets Each

See New Warnings Information & Directions
Compare to the Active Ingredients in
Tylenol® Cold
 Head Congestion

ConRx™ SEVERE COLD

Sore throat - Cough - Headache - Nasal Congestion

See New Warnings Information & Directions
Compare to the Active Ingredients in
Tylenol® Cold
 Head Congestion

ConRx™ SEVERE COLD

▲
 TO OPEN
 PUSH IN TAB AND PULL OUT

Compare to the Active Ingredients in
Tylenol® Cold Head Congestion

50 Pouches of 2 Caplets Each



50 Pouches of 2 Caplets Each

Sore throat - Cough - Headache - Nasal Congestion

ConRx™ SEVERE COLD

Compare to the Active Ingredients in
Tylenol® Cold Head Congestion
 See New Warnings Information & Directions

Drug Facts

Active ingredients (in each caplet)

Active ingredients (in each caplet)	Purposes
Acetaminophen 325 mg	Pain reliever
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- for the temporary relief of the following cold symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - cough
 - sinus congestion and pressure
 - to help loosen mucus and thin bronchial secretions to make coughs more productive

See New Warnings Information & Directions
Compare to the Active Ingredients in
Tylenol® Cold
 Head Congestion

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets 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.
- 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
- 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 exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 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 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 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. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

do not take more than directed (see overdose warning)

adults and children 12 years and over	take 2 caplets every 4 hours swallow whole - do not crush, chew or dissolve do not take more than 12 caplets in 24 hours
children under 12 years	do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- each caplet contains sodium 3 mg
- store between 20-25°C (68-77°F)
- do not use if card or pouch is torn or open
- see side panel for lot number and expiration date

Inactive ingredients

carnauba wax, croscarmellose sodium, D&C yellow #10 aluminum lake, flavor, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, shellac, sucralose, titanium dioxide

Questions or comments? 1-800-570-8650

ConRx™ SEVERE COLD

Sore throat - Cough - Headache - Nasal Congestant

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

*This product is not manufactured or distributed by: McNeil Consumer Speciality Pharmaceuticals Division of McNeil PPC, Inc. Eagle Distributors, Inc./ConRx™ does not own the Tylenol® Cold Head Congestion trademark.



Product manufactured by:
Eagle Distributors, Inc.
Los Angeles, CA 90011

CONRX COLD

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68737-232
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Dextromethorphan Hydrobromide (UNII: 9D2RT9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 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 DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
STARCH, CORN (UNII: O8232NY3SJ)	

POVIDONE K90 (UNII: RDH86HJV5Z)
GELATIN (UNII: 2G86QN327L)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
STEARIC ACID (UNII: 4ELV7Z65AP)
TALC (UNII: 7SEV7J4R1U)
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	YELLOW	Score	2 pieces
Shape	OVAL	Size	18mm
Flavor		Imprint Code	CRX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68737-232-16	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.