CONRX PM- acetaminophen and diphenhydramine 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.

ConRxTM PM

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	Nighttime sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver warning

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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.
- with any product containing diphenhydramine, even one used on skin n in children under 12 years of age
- 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
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

• sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

- pain gets worse or lasts more than 10 days n fever gets worse or lasts more than 3 days
- redness or swelling is present n new symptoms occur

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 at bedtime, do not take more than 2 caplets of this product 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

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

Inactive ingredients

croscarmellose sodium, FD&C blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, starch, stearic acid, titanium dioxide. May contain polyvinyl alcohol, silicon dioxide, sodium starch glycolate, talc.

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 PM®*

ConRxTM PM EXTRA STRENGTH

Pain Reliever Inighttime Sleep Aid

Acetaminophen, Diphenhydramine HCl

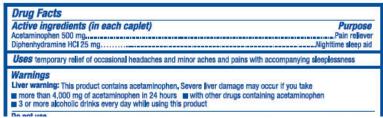
TO OPEN
PUSH IN TAB AND PULL OUT

Compare to the Active Ingredients in Tylenol $PM^{\otimes}*$

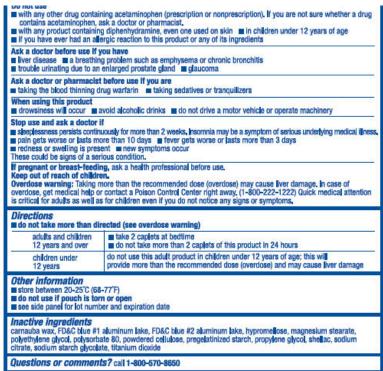
50 Pouches of 2 Caplets Each



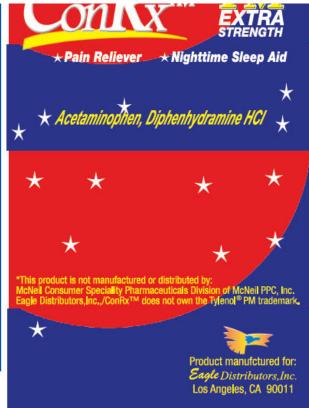








Contains No Aspirin



CONRX PM

acetaminophen and diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68737-235
Route of Administration	ORAL		

267Az Us

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Acetaminophen (UNII: 36209 ITL9D) (Acetaminophen - UNII:36209 ITL9D)	Acetaminophen	500 mg	
	Diphenhydramine Hydrochloride	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
ALUMINUM O XIDE (UNII: LMI26 O 6933)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYETHYLENE GLYCOL 6000 (UNII: 30 IQX730 WE)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PO WDERED CELLULO SE (UNII: SMD1X3XO9M)		

STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
SHELLAC (UNII: 46 N10 7B710)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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

Packaging			
# Item Code	e Package Description	Marketing Start Date	Marketing End Date
1 NDC:68737-235-19	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	part338	02/15/2013	

Labeler - Eagle Distributors,Inc. (929837425)

Revised: 2/2013 Eagle Distributors,Inc.