

NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled
PuraCap Pharmaceutical LLC

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.

Nighttime Cold & Flu

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- runny nose
- sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings

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

- more than 4 doses in 24 hrs, 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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters

- rash

If a skin reaction occurs, stop use and seek medical help right away.

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.

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- breathing problems such as emphysema or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

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. 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)**
- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

Other information

- store between 15-30°C (59-86°F)
- avoid excessive heat

Inactive ingredient

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

Questions or Comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Maximum Strength Nighttime Cold & Flu 16ct

compare to Mucinex Fast-Max Night Time Cold & Flu active ingredients

NDC 51013-193-14



MAXIMUM STRENGTH*

Night Time Cold & Flu

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.



NDC 51013-193-14



MAXIMUM STRENGTH*

Night Time Cold & Flu

Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Doxylamine succinate – Antihistamine
Phenylephrine HCl – Nasal Decongestant

- Relieves Aches, Fever and Sore Throat
- Relieves Runny Nose & Sneezing
- Relieves Nasal Congestion
- Controls Cough



**** Compare to the active ingredients in Mucinex® Fast-Max® Night Time Cold & Flu**

16 SOFTGELS

For Ages 12+

Night Time Cold & Flu

MAXIMUM STRENGTH*

*Per 4-hour dose. Do not take more than a total of 12 softgels in a 24-hour period.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

LOT NO:

EXP DATE:



0 93351 02397 2

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

**This product is not manufactured or distributed by Reckitt Benckiser, owner of the registered trademarks Mucinex® Fast-Max® Night Time Cold & Flu.

www.discount-drugmart.com
**DISTRIBUTED BY
 DRUG MART-FOOD FAIR
 MEDINA, OHIO 44256
 MADE IN CHINA**

SATISFACTION GUARANTEED
 IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED. IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256

DDM35-00

<p>Drug Facts</p> <p>Active Ingredients (In each softgel)</p> <p>Acetaminophen 325 mg.....Pain reliever/fever reducer Dextromethorphan HBr 10 mg.....Cough suppressant Doxylamine succinate 6.25 mg.....Antihistamine Phenylephrine HCl 5 mg.....Nasal decongestant</p>		<p>Purposes</p>
<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves these common cold and flu symptoms: <ul style="list-style-type: none"> cough nasal congestion minor aches and pains sore throat headache runny nose sneezing temporarily reduces fever controls cough to help you get to sleep 		
<p>Warnings</p> <p>Liver warning This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> more than 12 softgels in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen 3 or more alcoholic drinks daily while using this product <p>Allergy alert Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> skin reddening blisters rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>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.</p>		
<p>Do not use</p> <ul style="list-style-type: none"> 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. 		
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> liver disease heart disease diabetes high blood pressure thyroid disease glaucoma trouble urinating due to an enlarged prostate gland breathing problems such as emphysema or chronic bronchitis cough that occurs with too much phlegm (mucus) persistent or chronic cough such as occurs with smoking, asthma, or emphysema 		
<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> taking the blood thinning drug warfarin taking sedatives or tranquilizers <p>When using this product</p> <ul style="list-style-type: none"> do not use more than directed excitability may occur, especially in children marked drowsiness may occur alcohol, sedatives, and tranquilizers may increase drowsiness avoid alcoholic drinks be careful when driving a motor vehicle or operating machinery <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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. <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p>		
<p>Directions</p> <ul style="list-style-type: none"> do not take more than directed (see Overdose warning) do not take more than 12 softgels in any 24-hour period adults and children 12 years of age and older: take 2 softgels every 4 hours children under 12 years of age: do not use 		
<p>Other information</p> <ul style="list-style-type: none"> store between 15-30°C (59-86°F) avoid excessive heat 		
<p>Inactive Ingredients</p> <p>D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white edible ink</p>		
<p>Questions or comments?</p> <p>Call toll free: 1-800-833-6278</p>		

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-193
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: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green (clear)	Score	no score
Shape	capsule (oblong)	Size	21mm
Flavor		Imprint Code	PC22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-193-14	2 in 1 CARTON	07/14/2017	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/14/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-193) , analysis(51013-193)