DAY SEVERE COLD AND NIGHT COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride
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.

Day Severe Cold and Night Cold and Flu

Active ingredients (in each liquid gel)

Day Severe Cold & Flu

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Night Severe Cold & Flu

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purpose

Day Severe Cold & Flu

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Night Severe Cold & Flu

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - headache
  - nasal congestion
  - sore throat
  - runny nose and sneezing ***(NIGHT only)***
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ***(DAY only)***
- controls cough to help you get to sleep ***(NIGHT only)***
- temporarily reduces fever

Warnings

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

- more than 12 liquid gels 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

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, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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
- trouble urinating due to an enlarged prostate gland
- glaucoma ***(NIGHT only)***
- a breathing problem such as emphysema or chronic bronchitis ***(NIGHT only)***
- 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
- taking sedatives or tranquilizers ***(NIGHT only)***

When using this product

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

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion 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 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

Other information

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

Inactive ingredients

DAY only: FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

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

Questions or comments?

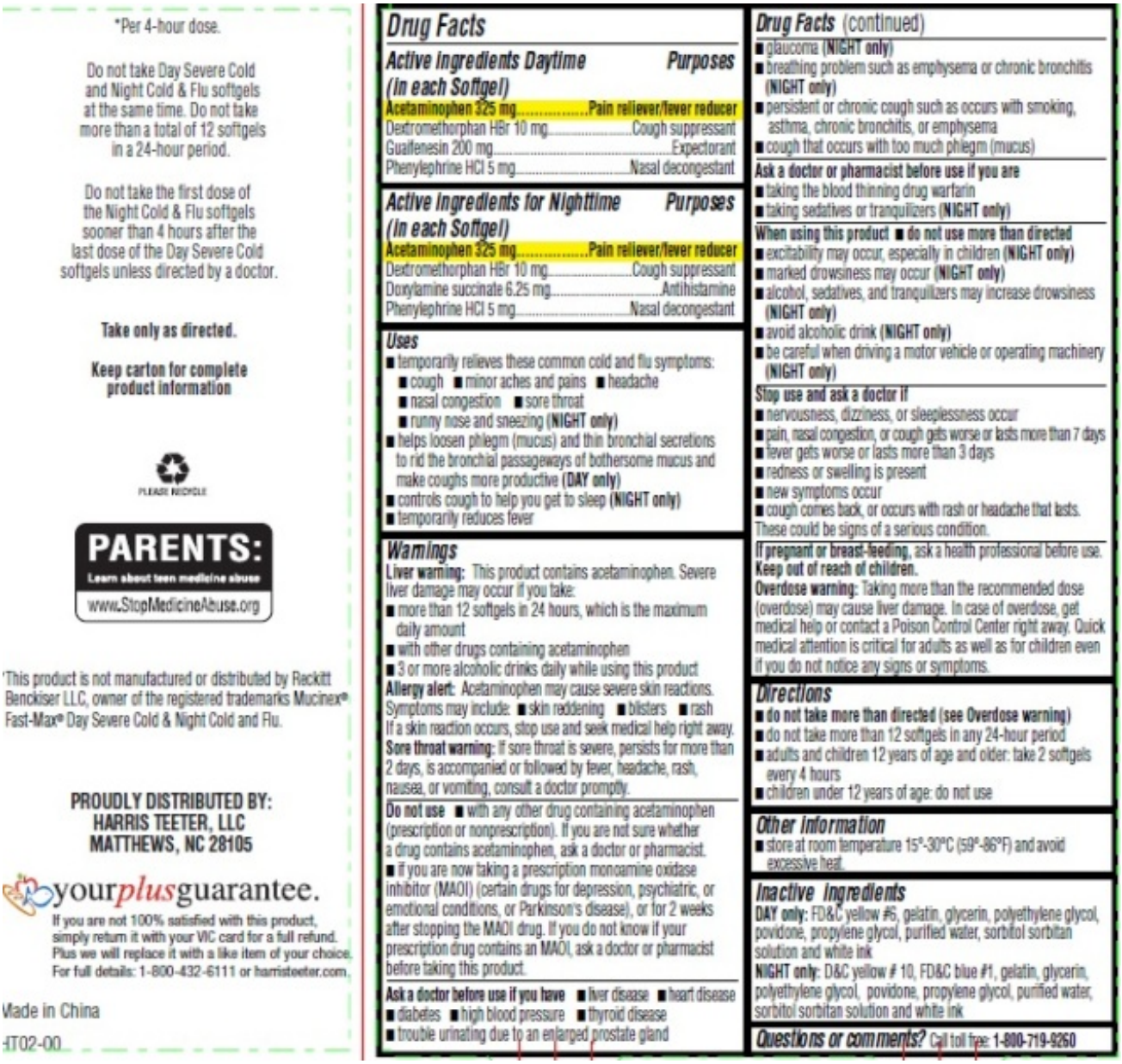
Call toll free: **1-800-719-9260**

PRINCIPAL DISPLAY PANEL

Day and Night Severe Cold & Flu Combo 24ct

NDC 51013-416-04


Day
Night
SEVERE COLD
COLD & FLU
NDC 51013-416-04
Harris Teeter
**Compare to the active ingredients in Mucinex® Fast-Max® Day Severe Cold & Night Cold and Flu
• Acetaminophen
Pain Reliever/Fever Reducer
• Dextromethorphan HBr
Cough Suppressant
• Guaifenesin
Expectorant
• Phenylephrine HCl
Nasal Decongestant
• Relieves Aches, Fever & Sore Throat
• Controls Cough
• Relieves Nasal & Chest Congestion
• Thins & Loosens Mucus
Actual Size
16 Softgels
• Acetaminophen
Pain Reliever/Fever Reducer
• Dextromethorphan HBr
Cough Suppressant
• Doxylamine succinate
Antihistamine
• Phenylephrine HCl
Nasal Decongestant
• Relieves Aches, Fever & Sore Throat
• Controls Cough
• Relieves Nasal Congestion
• Relieves Runny Nose & Sneezing
Actual Size
8 Softgels
0 72036 72776 3



*Per 4-hour dose.

Do not take Day Severe Cold and Night Cold & Flu softgels at the same time. Do not take more than a total of 12 softgels in a 24-hour period.

Do not take the first dose of the Night Cold & Flu softgels sooner than 4 hours after the last dose of the Day Severe Cold softgels unless directed by a doctor.

Take only as directed.

Keep carton for complete product information

PLEASE RECYCLE

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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

PROUDLY DISTRIBUTED BY:
HARRIS TEETER, LLC
MATTHEWS, NC 28105

yourplusguarantee.
If you are not 100% satisfied with this product, simply return it with your VIC card for a full refund. Plus we will replace it with a like item of your choice. For full details: 1-800-432-6111 or harristeeter.com.

Made in China

4T02-00

Drug Facts

Active Ingredients Daytime (In each Softgel) — **Purposes**

Acetaminophen 325 mg	**Pain reliever/fever reducer**
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active Ingredients for Nighttime (In each Softgel) — **Purposes**

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

Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - headache
  - nasal congestion
  - sore throat
  - runny nose and sneezing (**NIGHT only**)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (**DAY only**)
- controls cough to help you get to sleep (**NIGHT only**)
- temporarily reduces fever

Warnings

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

- 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

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
- trouble urinating due to an enlarged prostate gland

Drug Facts (continued)

- glaucoma (**NIGHT only**)
- breathing problem such as emphysema or chronic bronchitis (**NIGHT only**)
- 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
- taking sedatives or tranquilizers (**NIGHT only**)

When using this product ■ do not use more than directed

- excitability may occur, especially in children (**NIGHT only**)
- marked drowsiness may occur (**NIGHT only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**NIGHT only**)
- avoid alcoholic drink (**NIGHT only**)
- be careful when driving a motor vehicle or operating machinery (**NIGHT only**)

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 at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive Ingredients

DAY only: FD&C yellow #5, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink
NIGHT only: D&C yellow # 10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

Questions or comments? Call toll free: 1-800-719-9260

DAY SEVERE COLD AND NIGHT COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51013-416

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-416-04	1 in 1 CARTON; Type 0: Not a Combination Product	08/29/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16

Part 2	1 BLISTER PACK	8

Part 1 of 2

DAY SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

Product Information

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
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE (clear)	**Score**	no score
Shape	CAPSULE (Oblong)	**Size**	25mm
Flavor		**Imprint Code**	PC26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
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	08/29/2017	

Part 2 of 2

NIGHT SEVERE COLD AND FLU

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

Product Information

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: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	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)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	

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		1 in 1 CARTON		
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	08/29/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/29/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(51013-416) , analysis(51013-416)

Revised: 11/2019 PuraCap Pharmaceutical LLC