NITE TIME COLD AND FLU- acetaminophen, phenylephrine hydrochloride, doxylamine succinate, dextromethorphan hydrobromide 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.

Nite Time Cold & Flu

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
  - minor aches and pains
  - headache
  - nasal and sinus congestion
  - cough
  - sore throat
  - runny nose
  - sneezing
- temporarily reduces fever

Warnings

Liver warning

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

- more than 10 softgels 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

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.

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.

Do not use to sedate children.

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.
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- 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 exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- pain, cough, 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.
- nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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 the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

- store at room temperature. Avoid excessive heat.

Inactive ingredients

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 - 8ct

Nite Time Cold & Flu 8 SOFTGELS

NDC 51013-400-06

*Compare to the active ingredients in Alka-Seltzer PLUS® Night Cold and Flu Formula

PuraVation.

NiteTime
Cold & Flu
Multi-Symptom Relief
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

8 LIQUID-FILLED SOFTGELS

31

NDC 51013-400-06

*Compare to the active ingredients in Alka-Seltzer Plus® Night Cold & Flu Formula

PuraVation.

NiteTime
Cold & Flu
Multi-Symptom Relief
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

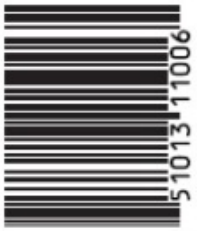
Actual Size

Nasal Congestion, Cough, Runny Nose, Headache & Body Ache, Sore Throat

8 LIQUID-FILLED SOFTGELS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

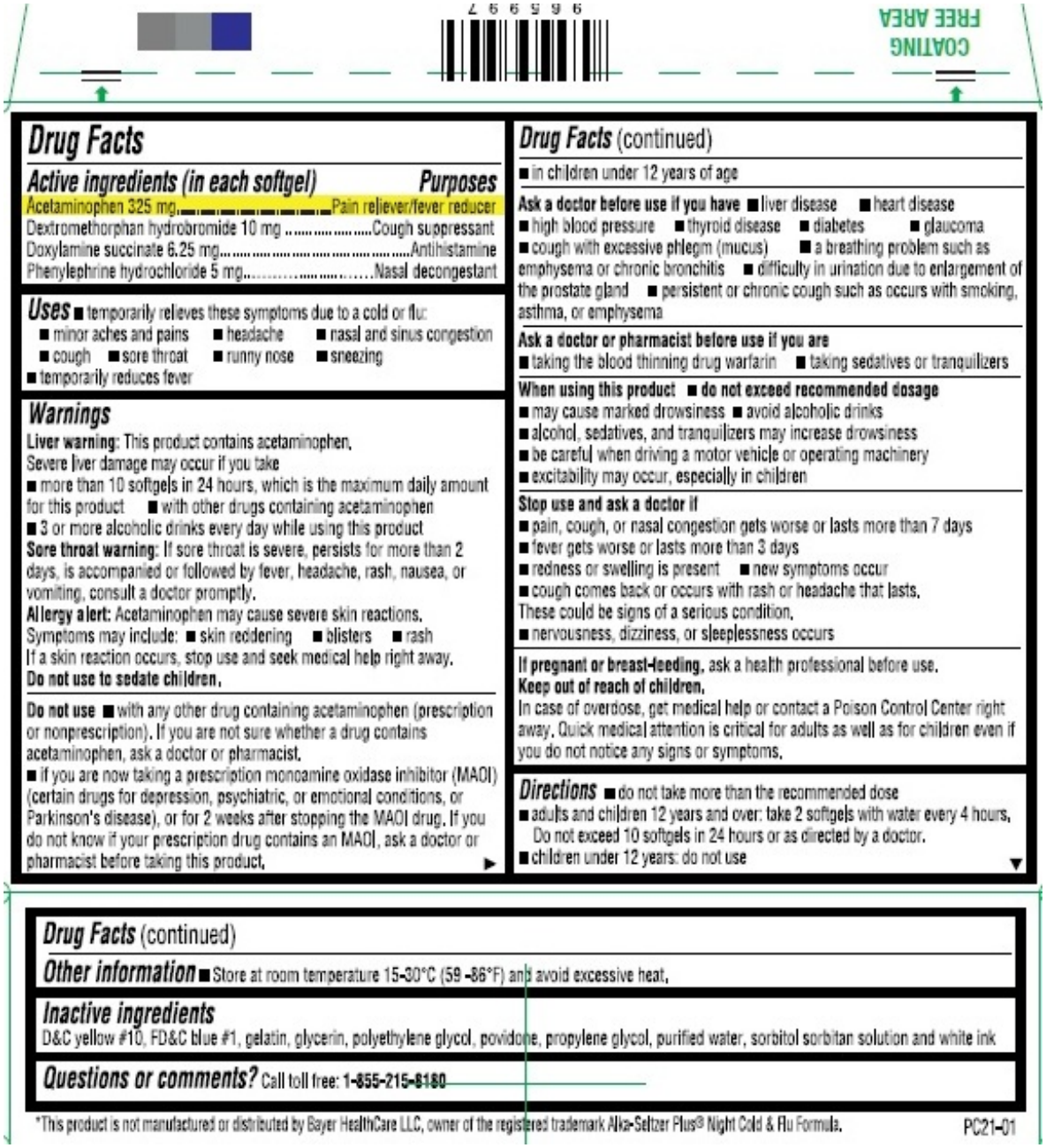
THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.



Distributed By: PuraCap Pharmaceutical LLC
20 Kingsbridge Road, Piscataway, NJ 08854
Made in China

LOT NO:
EXP DATE:

COATING FREE AREA



Drug Facts

Active ingredients (in each softgel) — **Purposes**

Acetaminophen 325 mg — Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg — Cough suppressant
Doxylamine succinate 6.25 mg — Antihistamine
Phenylephrine hydrochloride 5 mg — Nasal decongestant

Uses ■ temporarily relieves these symptoms due to a cold or flu:
■ minor aches and pains ■ headache ■ nasal and sinus congestion
■ cough ■ sore throat ■ runny nose ■ sneezing
■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen.
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Drug Facts (continued)

■ in children under 12 years of age

Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ cough with excessive phlegm (mucus) ■ a breathing problem such as emphysema or chronic bronchitis ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema

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■ adults and children 12 years and over: take 2 softgels with water every 4 hours, Do not exceed 10 softgels in 24 hours or as directed by a doctor.
■ children under 12 years: do not use ▼

Drug Facts (continued)

Other information ■ Store at room temperature 15-30°C (59 -86°F) and avoid excessive heat.

Inactive ingredients
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: 1-855-215-8180

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Alka-Seltzer Plus® Night Cold & Flu Formula. PC21-01

PRINCIPAL DISPLAY PANEL - 10ct

Nite Time Cold & Flu 10 SOFTGELS

NDC 51013-400-01

*Compare to the active ingredients in Alka-Seltzer PLUS® Night Cold and Flu Formula

PuraVation.

NiteTime
Cold & Flu
Multi-Symptom Relief

10 LIQUID-FILLED SOFTGELS

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

NDC 51013-400-01

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PuraVation.

NiteTime
Cold & Flu
Multi-Symptom Relief

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

Actual Size

Nasal Congestion, Cough, Runny Nose, Headache & Body Ache, Sore Throat

10 LIQUID-FILLED SOFTGELS

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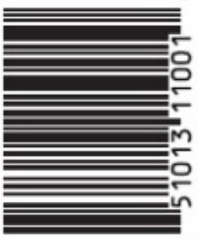

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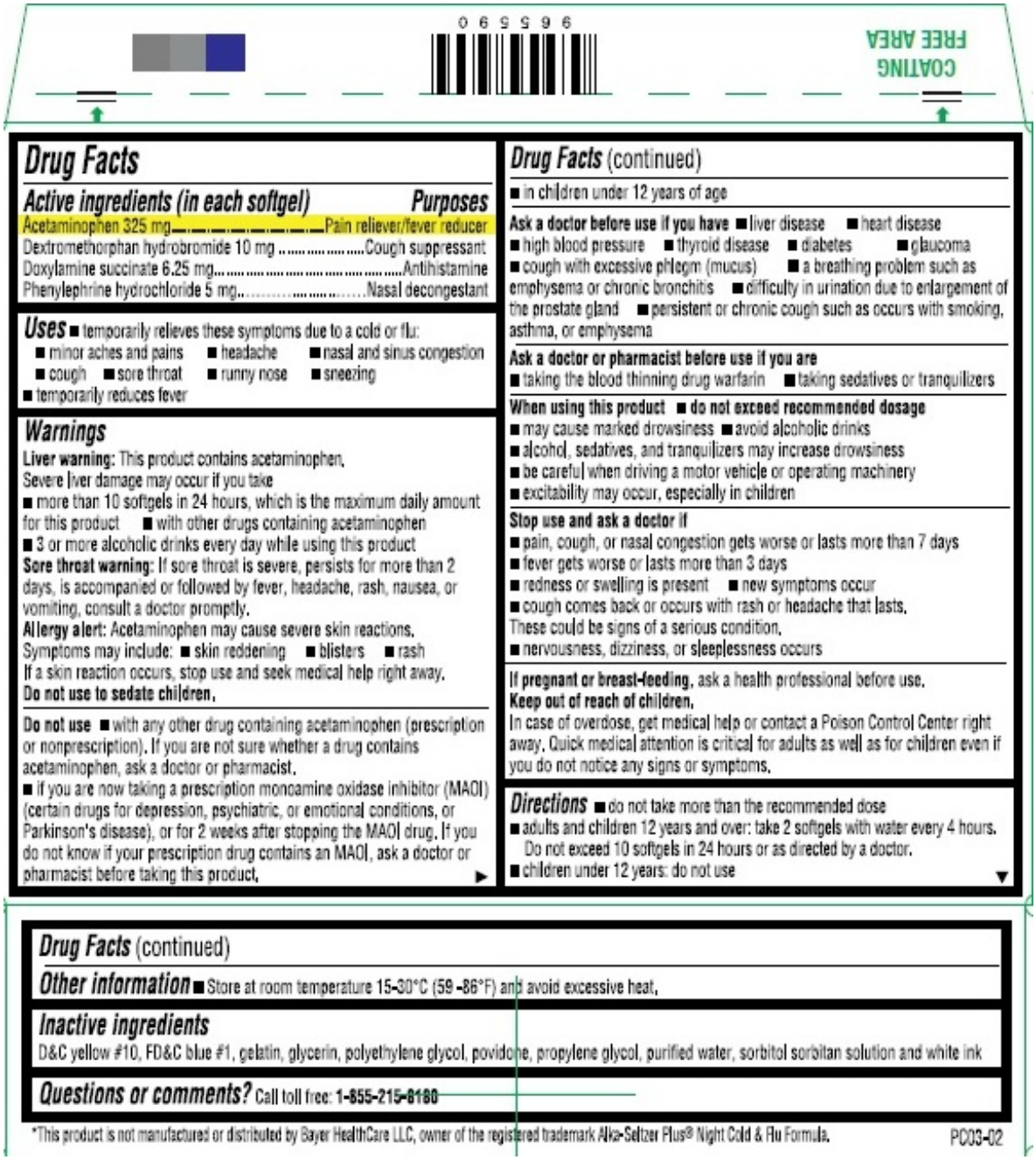

NITE TIME COLD AND FLU

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51013-400
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	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:51013-400-06	1 in 1 CARTON	07/17/2017	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51013-400-01	1 in 1 CARTON	07/17/2017	
2		10 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	07/17/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(51013-400) , analysis(51013-400)