DDM DAY TIME AND NITE TIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, 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 TIME and NITE TIME COLD/FLU LIQUID CAPS

Active ingredients (in each softgel)

Active ingredients for Nighttime (in each Softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Active ingredients for Daytime (in each Softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purposes

DDM NITE TIME COLD/FLU LIQUID CAPS

Pain reliever/fever reducer

Cough suppressant

Antihistamine

DDM DAY TIME COLD/FLU LIQUID CAPS

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing (Nighttime only)
- nasal congestion (Daytime only)

Liver warning

These products contain acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hrs, which is the maximum daily amount for these products
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

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
- 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.
- to make a child sleep (Nighttime only)

Ask a doctor before use if you have
- liver disease
- heart disease (Daytime only)
- thyroid disease (Daytime only)
- diabetes (Daytime only)
- high blood pressure (Daytime only)
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to an enlarged prostate gland
- glaucoma (Nighttime only)

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers (Nighttime only)
- taking the blood thinning drug warfarin

When using these products
- **do not use more than directed**

In addition, when using Nighttime:

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if
- you get nervous, dizzy, or sleepless (Daytime only)

- pain, cough or nasal congestion (Daytime only) gets worse or last more than 7 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- 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 can cause serious health problems. 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

- take only as directed - see Overdose warning
- Take Nighttime or Daytime
- do not exceed 4 doses per 24 hrs

Age	Daytime	Nighttime
adults and children 12 yrs & over	2 softgels with water every 4 hrs	2 softgels with water every 6 hrs
children 4 to under 12 yrs	ask a doctor	ask a doctor
children under 4 yrs	**do not use**	**do not use**

- **When using other Daytime or Nighttime products, carefully read each label to ensure correct dosing**

Other information

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

Inactive ingredients

Daytime: FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special and white edible ink

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

Questions or comments?

Call toll free: **1-800-833-6278**

Principle Display Panel

DDM DAT TIME and NITE TIME COLD/FLU LIQUID CAPS

NDC 51013-141-08

*Compare to the active ingredients in VICKS® DayQuil® and NyQuil® Cold and Flu LiquiCaps®

DDM DAY TIME AND NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51013-141

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-141-08	1 in 1 CARTON; Type 0: Not a Combination Product	06/20/2016	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	10
Part 2	1 BLISTER PACK	10

Part 1 of 2

DAY TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, 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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC9

Contains	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 CARTON		
1		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	06/20/2016	

Part 2 of 2

NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate 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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 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)	

Product Characteristics			
Color	green (clear)	**Score**	no score

Shape	capsule (oblong)	**Size**	20mm
Flavor		**Imprint Code**	PC10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		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	06/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/20/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(51013-141) , analysis(51013-141)

Revised: 12/2019 PuraCap Pharmaceutical LLC