#### 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

" T. C. I		Package Descriptio					- 1-	
# Item Code				ting Start Date	Marketii	ng End Date		
1 NDC:51013-141-08	1 in 1 CARTON; Type 0: Not a Combination Product 06/2			06/20/2	0.16			
Quantity of Parts	5							
Part #				Total Product Quantity				
Part 1 1 BLISTER PA	<b>U</b> -		10			5		
Part 2 1 BLISTER PA	.CK		10					
Part 1 of 2								
DAY TIME C	OLD AND	FLU						
acetaminophen, de	xtromethorpha	n hydrobromide, ph	enylephrine h	ydrochlo	ride capsule, liqu	uid filled		
Product Informa	tion							
Route of Administra	ation	ORAL						
Active Ingredien	nt/Active Moi	ety						
	Ingr	edient Name			Basis of St	rength	Strengt	
ACETAMINOPHEN (U	•	<b>edient Name</b> D) (ACETAMINOPHEN ·	- UNII:362O9IT	L9D)	Basis of St ACETAMINOPHEN	-	<b>Strengt</b> 325 mg	
	JNII: 362O9ITL9I IAN HYDROBRO	D) (ACETAMINOPHEN) DMIDE (UNII: 9 D2RTI9)		L9D)		1		
DEXTROMETHORPH	JNII: 36209ITL9I <b>IAN HYDROBRO</b> AN - UNII:7355X3	D) (ACETAMINOPHEN) DMIDE (UNII: 9 D2RTI9)	KYH)	,	ACETAMINOPHEN DEXTROMETHOR	1		
DEXTROMETHORPH (DEXTROMETHORPH PHENYLEPHRINE HY	JNII: 36209ITL9I <b>IAN HYDROBRO</b> AN - UNII:7355X3	D) (ACETAMINOPHEN D <b>MIDE</b> (UNII: 9 D2RTI9) ROTS)	KYH)	,	ACETAMINOPHEN DEXTROMETHOR HYDROBROMIDE	1	325 mg 10 mg	
DEXTROMETHORPH (DEXTROMETHORPH/ PHENYLEPHRINE HY UNII:1WS297W6MV)	JNII: 36209ITL9I IAN HYDROBRO AN - UNII:7355X3 DROCHLORIDH	D) (ACETAMINOPHEN D <b>MIDE</b> (UNII: 9 D2RTI9) ROTS) E (UNII: 04JA59TNSJ) (	KYH) PHENYLEPHRIN	,	ACETAMINOPHEN DEXTROMETHOR HYDROBROMIDE	N PHAN	325 mg 10 mg 5 mg	
DEXTROMETHORPH (DEXTROMETHORPH PHENYLEPHRINE HY UNII:1WS297W6MV) Inactive Ingredie	JNII: 36209ITL9I IAN HYDROBRO AN - UNII:7355X3 TDROCHLORIDH	D) (ACETAMINOPHEN DMIDE (UNII: 9 D2RTI91 ROTS) E (UNII: 04JA59TNSJ) ( Ingredient N	KYH) PHENYLEPHRIN	,	ACETAMINOPHEN DEXTROMETHOR HYDROBROMIDE	N PHAN	325 mg 10 mg	
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DEXTROMETHORPH (DEXTROMETHORPH PHENYLEPHRINE HY UNII: 1WS 297W6 MV) Inactive Ingredic FD&C RED NO. 40 (U FD&C YELLOW NO.	JNII: 36209ITL9I IAN HYDROBRO AN - UNII:7355X3 TDROCHLORIDH ents JNII: WZB9127XC 6 (UNII: H77VEIS	D) (ACETAMINOPHEN DMIDE (UNII: 9 D2RTI91 ROTS) E (UNII: 04JA59TNSJ) ( Ingredient N DA)	KYH) PHENYLEPHRIN	,	ACETAMINOPHEN DEXTROMETHOR HYDROBROMIDE	N PHAN	325 mg 10 mg 5 mg	
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Contains									
Packaging									
# Item Code			Package D	escription		Marke	ting Start Date	Marke	ting End Date
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Marketing									
Marketing Ca			ation Numb	er or Monograph (	Citation		eting Start Date	Marke	eting End Date
OTC monograph	final	part341				06/20/	2016		
Part 2 of 2	2								
NITE TIM	IE CC	DLD A	ND FLU						
				bromide, doxylam	ine succin	ate ca	psule, liquid filled		
r	,		F	; <u>j</u> j					
Product Info	rmatio	n							
Route of Admi	nistratio	on	ORAL						
Active Ingre	dient//	Active <b>N</b>	Ioiety						
		Iı	ngredient N	lame			Basis of Str	ength	Strength
ACETAMINOPH	<b>EN</b> (UNI	I: 362O9T	ГL9D) (ACET.	AMINOPHEN - UNII:3	62O9ITL9E	))	ACETAMINOPHEN		325 mg
DEXTROMETHO (DEXTROMETHO				NII: 9 D2RTI9 KYH)			DEXTROMETHORP HYDROBROMIDE	HAN	15 mg
DOXYLAMINE	SUCCIN	ATE (UNII	: V9 B I9 B 5 Y 12	) (DOXYLAMINE - U	NII:95QB77	JKPL)	DOXYLAMINE SUC	CINATE	6.25 mg
Inactive Ing	redien	ts							
			In	gredient Name					Strength
D&C YELLOW									
FD&C BLUE NO			BTBD)						
GELATIN (UNII:	-	,							
GLYCERIN (UN									
			PECIFIED (U	NII: 3WJQ0SDW1A)					
POVIDONE (UN									
PROPYLENE GI WATER (UNII: 0			29Q10/V3)						
SORBITOL (UN									
<b>Product Cha</b>	racter	istics							
Color		green (o	clear)		Score			no sc	ore

Shape		capsule (oblong)	Size		20 mm	
Flavor			Imprint	Code	PC10	
Contains						
Packaging						
# Item Code		Package Description		Marketing Start Date	Marketing End Date	
1	1 in 1 CA	RTON				
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# 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