

DAY TIME COLD FLU MEDICINE- acetaminophen, dextromethorphan hydrobromide, 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.

DAY TIME LIQUID CAPS

Drug Facts

Active ingredients (in each Softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- 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

- 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
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with excessive phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product, do not use more than directed.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- 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 directed 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 & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed - see **Overdose warning**
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

- **when using other Daytime or Nighttime products, carefully read each label to insure correct**

dosing

Other information

- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

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

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

DAY TIME LIQUID CAPS 20 SOFTGELS

NDC 51013-189-08

*Compare to the active ingredients in VICKS® DayQuil®

DAY TIME

LIQUID CAPS

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

STORE AT ROOM TEMPERATURE
AVOID EXCESSIVE HEAT.



DISCOUNT
drug mart
FOOD FAIR

NDC 51013-189-08

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DAY TIME

LIQUID CAPS

ADULT DAY TIME COLD/FLU MEDICINE

**ACETAMINOPHEN,
Dextromethorphan HBr, Phenylephrine HCl,
PAIN RELIEVER • FEVER REDUCER
COUGH SUPPRESSANT • NASAL DECONGESTANT**

RELIEVES MAJOR COLD & FLU-LIKE SYMPTOMS



20 SOFTGELS

*Compare to the active ingredients in VICKS® DayQuil®

Non-Drowsy

QUESTIONS OR COMMENTS? call toll free: 1-800-833-8278

Drug Facts (continued)

Other Information

Keep out of reach of children. See important warnings below.

Keep this and all other medicines out of the reach of children. See important warnings below.

Keep this and all other medicines out of the reach of children. See important warnings below.

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Drug Facts (continued)

Warnings

Do not use if you are allergic to any of the ingredients. See important warnings below.

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COATING FREE AREA

Drug Facts (continued)

Directions

Adults and children 12 years of age and older: Take 2 capsules with water every 4 to 6 hours. Do not exceed 4 doses per 24 hours.

Children 6 to 11 years: Take 1 capsule with water every 4 to 6 hours. Do not exceed 4 doses per 24 hours.

Children 4 to 5 years: Take 1 capsule with water every 4 to 6 hours. Do not exceed 4 doses per 24 hours.

Children 2 to 3 years: Take 1 capsule with water every 4 to 6 hours. Do not exceed 4 doses per 24 hours.

Children 1 to 3 years: Take 1 capsule with water every 4 to 6 hours. Do not exceed 4 doses per 24 hours.

COATING FREE AREA

DAY TIME COLD FLU MEDICINE			
acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-189
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 HYDROCHLORIDE	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	NDC:51013-189-08	2 in 1 CARTON	10/06/2016	
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	10/06/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(51013-189) , analysis(51013-189)