

**DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled**  
**Chain Drug Marketing Association Inc.**

*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.*

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**DayTime Cold & Flu**

**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 these symptoms due to a cold or flu:
- minor aches and pains
- headache
- cough
- sore throat
- nasal and sinus congestion
- 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**

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- 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
- cough with excessive phlegm (mucus)
- 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

### **When using this product do not exceed recommended dosage**

#### **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 15°C-30°C (59°F-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: 248-449-9300

**PRINCIPAL DISPLAY PANEL**

DayTime Cold & Flu 20 SOFTGELS

NDC 63868-864-20

\*Compare to the active ingredients in Alka-Seltzer



**Multi-Symptom, Non-Drowsy  
DayTime**  
Cold & Flu

NDC 63868-864-20

QC QUALITY CHOICE

\*SATISFACTION GUARANTEED\*

4357 W. Nine Mile  
Novi, MI 48376-0995  
www.daytimecoldandflu.com  
Questions: 248-449-9300

Distributed by CDMAA, Inc.<sup>®</sup>

\*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Alka-Seltzer PLUS<sup>®</sup>.

\*Compare to Alka-Seltzer PLUS<sup>®</sup>  
Day Cold and Flu Formula

**Multi-Symptom, Non-Drowsy  
DayTime**  
Cold & Flu

Acetaminophen 325 mg | Pain Reliever/Fever Reducer  
Dextromethorphan HBr 10 mg | Cough Suppressant  
Phenylephrine HCl 5 mg | Nasal Decongestant

**For Relief of:**  
Nasal Congestion | Cough | Sinus Pressure  
Headache & Body Ache | Sore Throat





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CDMA05-00  
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

LOT NO:  
EXP DATE:

MADE IN CHINA

STORE AT ROOM TEMPERATURE  
AVOID EXCESSIVE HEAT.

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

COATING FREE AREA

COATING FREE AREA

**20 Liquid Gels**

<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> do not take more than the recommended dose adults and children 12 years of age and over: take 2 softgels in water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor. children under 12 years of age: do not use</p> <p><b>Inactive Ingredients</b> FD&amp;C red #40, FD&amp;C yellow #6, gelatin, glycerin, polyethylene glycol, polyethylene glycol, purified water, sorbitol, natural flavors, and white edible ink</p> <p><b>Other Information</b> store at room temperature and avoid excessive heat</p> <p><b>Questions or comments?</b> Call 248-449-9300</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b> 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 5 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. 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. 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.</p> <p><b>Uses</b> temporarily relieves these symptoms due to a cold or flu: minor aches and pains ■ headache ■ cough temporarily reduces fever ■ sore throat ■ nasal and sinus congestion temporarily reduces fever</p> <p><b>Active Ingredients (in each softgel) Purpose</b> Acetaminophen 325 mg Pain reliever/fever reducer Dextromethorphan HBr 10 mg Cough suppressant Phenylephrine HCl 5 mg (Nasal) decongestant</p> <p><b>Ask a doctor before use if you have</b> liver disease ■ heart disease ■ high blood pressure thyroid disease ■ diabetes ■ cough with excessive phlegm (mucus) ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema</p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</b></p> <p><b>When using this product do not exceed the recommended dosage</b></p> <p><b>Stop use and ask a doctor if</b> ■ 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</p> <p><b>If pregnant or breast-feeding, ask a health professional before use.</b></p>
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COATING FREE AREA

<b>DAYTIME COLD AND FLU</b>			
acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-864
<b>Route of Administration</b>	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: 059QF0K00R)	
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:63868-864-20	2 in 1 CARTON	03/08/2017	
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	03/08/2017	

**Labeler** - Chain Drug Marketing Association Inc. (011920774)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(63868-864) , analysis(63868-864)

