

**DAYTIME NIGHTTIME COLD FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl  
APNAR PHARMA LP**

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**DAYTIME NIGHTTIME COLD FLU RELIEF**

**Active ingredients** for Daytime *(in each softgel)*

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Active ingredients** for Nighttime *(in each softgel)*

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Purposes**

for Daytime

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Purposes**

for Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Uses**

Daytime

- temporarily relieves common cold and flu symptoms
- cough due to minor throat and bronchial irritation
- nasal congestion
- headache
- minor aches and pains
- Fever
- sore throat

**Uses**

Nighttime

- temporarily relieves common cold and flu symptoms
- cough due to minor throat and bronchial irritation

- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

## **Warnings**

Daytime

**Liver warning:** These products contain acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this products

**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

**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.

Nighttime

**Liver warning:** These products contain acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this products

**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

**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**

Daytime

- 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.

#### Nighttime

- 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**

#### Daytime

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

#### Nighttime

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland

### **Ask a doctor or pharmacist before use if you are**

#### Daytime

taking the blood thinning drug warfarin

#### Nighttime

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

#### Daytime

do not exceed recommended dosage

#### Nighttime

- do not exceed recommended dosage
- excitability may occur, especially in children

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

### **Stop use and ask a doctor if**

#### Daytime

- nervousness, dizziness or sleeplessness occur
- pain, cough, and nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

#### Nighttime

- pain or cough 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 headache that lasts.

These could be a 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 liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222- 1222) 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***

#### Daytime

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve

**adults and children 12 years and over:** take 2 softgels with water every 4 hours.

**children under 12 years:** do not use

#### Nighttime

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve

**adults and children 12 years and over:** take 2 softgels with water every 6 hours

**children under 12 years:** do not use

***Other information***

- store between 15-30°C (59-86°F)
- avoid excessive heat

***Inactive ingredients***

Daytime

Gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, FD&C yellow #6, FD&C Red #40 , white ink

Nighttime

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

***Questions or comments?***

Call 1-855-642-2594

†Compare to the active ingredients in Vicks® DayQuil® and NyQuil® Cold & Flu LiquiCaps®

Daytime

NDC 24689-152-01

Multi-Symptom Cold & Flu Relief

Acetaminophen 325 mg- Pain reliever / Fever reducer

Dextromethorphan HBr 10 mg - Cough suppressant

Phenylephrine HCl 5 mg - Nasal decongestant

Relieves:

- Aches, fever, sore throat
- Cough
- Nasal congestion

Non-drowsy

Alcohol-Free

Antihistamine-Free

Softgels\*\*

(\*\* Liquid-filled capsules)

Nighttime

Multi-Symptom Cold & Flu Relief

Acetaminophen 325 mg - Pain reliever / Fever reducer

Dextromethorphan HBr 15 mg - Cough suppressant

Doxylamine succinate 6.25 mg - Antihistamine

Relieves:

- Aches, fever, sore throat
- Cough
- Runny nose, sneezing

Softgels\*\*

Alcohol-free

(\*\*Liquid-filled capsules)

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

†This product is not manufactured or distributed by The Procter & Gamble Company.

Vicks®, DayQuil®, NyQuil®, and LiquiCaps® are registered trademarks of the Procter and Gamble Company.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOW SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by:

**APNAR PHARMA LP**

CHINO, CA, USA, 91710

Rev.: 04/2023

# GLUE FRONT SIDE - N.C.

GLUE FRONT SIDE NO COATING

GLUE FRONT SIDE NO COATING

**Drug Facts (continued)**

**Ask a doctor before use if you have:** • liver disease • heart disease • high blood pressure • cough that occurs with too much phlegm (mucus) • a breathing problem or chronic bronchitis • trouble urinating due to an enlarged prostate gland • emphysema • trouble urinating due to an enlarged prostate gland • blood thinning drug warfarin • taking sedatives or tranquilizers

**When using this product:** • do not exceed recommended dosage • excitability may occur, especially in children • marked drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if:** • new symptoms occur • cough comes back or occurs with rash more than 7 days • head or neck congestion gets worse or lasts more than 7 days • head or neck pain or sore throat lasts more than 7 days • fever or sinus pain or sore throat lasts more than 7 days • you have a severe allergic reaction to acetaminophen

**Keep out of reach of children. Overdose warning:** Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1232) 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 directed (see Overdose warning) • do not take more than 4 doses in 24 hours • swallow whole; do not crush, chew, or dissolve

**Other information** • store between 15-30°C (59-86°F) • avoid excessive heat

**Inactive ingredients** Gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, FD&C yellow #6, FD&C Red #40, white ink

**Questions or comments?** Call 1-855-642-2594

**Drug Facts (continued)**

**Ask a doctor before use if you are taking the following:** • blood thinning drug warfarin • taking sedatives or tranquilizers • smoking, asthma, or emphysema • persistent or chronic cough such as occurs with whooping cough • trouble urinating due to an enlarged prostate gland • emphysema • trouble urinating due to an enlarged prostate gland • blood thinning drug warfarin • taking sedatives or tranquilizers

**Ask a doctor before use if you have:** • liver disease • heart disease • high blood pressure • cough that occurs with too much phlegm (mucus) • a breathing problem or chronic bronchitis • trouble urinating due to an enlarged prostate gland • emphysema • trouble urinating due to an enlarged prostate gland • blood thinning drug warfarin • taking sedatives or tranquilizers

**When using this product:** • do not exceed recommended dosage • excitability may occur, especially in children • marked drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if:** • new symptoms occur • cough comes back or occurs with rash more than 7 days • head or neck congestion gets worse or lasts more than 7 days • head or neck pain or sore throat lasts more than 7 days • fever or sinus pain or sore throat lasts more than 7 days • you have a severe allergic reaction to acetaminophen

**Keep out of reach of children. Overdose warning:** Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1232) 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 directed (see Overdose warning) • do not take more than 4 doses in 24 hours • swallow whole; do not crush, chew, or dissolve

**Other information** • store between 15-30°C (59-86°F) • avoid excessive heat

**Inactive ingredients** D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

**Questions or comments?** Call 1-855-642-2594

Lot: NO VARNISH  
Exp: AREA

Distributed By:  
**APNAR PHARMA LP**  
CHINO, CA, USA, 91710

**PARENTS:**  
Learn about tamper-resistant unit  
www.StampOutTampering.com

N 3 246891152011

†Compare to the active ingredients in Vicks® DayQuil® and NyQuil® Cold & Flu LiquiCaps®

NDC 24689-152-01

**DAYTIME**  
Multi-Symptom Cold & Flu Relief

Acetaminophen 325 mg  
Pain reliever / Fever reducer

Dextromethorphan HBr 10 mg  
Cough suppressant

Phenylephrine HCl 5 mg  
Nasal decongestant

**Relieves:**

- Aches, fever, sore throat
- Cough
- Nasal congestion

Non-drowsy Alcohol-Free Antihistamine-Free  
Softgels\*\* (\*\* Liquid-filled capsules)

**NIGHTTIME**  
Multi-Symptom Cold & Flu Relief

Acetaminophen 325 mg  
Pain reliever / Fever reducer

Dextromethorphan HBr 15 mg  
Cough suppressant

Doxylamine Succinate 6.25 mg  
Antihistamine

**Relieves:**

- Aches, fever, sore throat
- Cough
- Runny nose, sneezing

Softgels\*\* Alcohol-Free  
(\*\* Liquid-filled capsules)

**32 softgels DAY & NIGHT COMBO PACK 16 softgels**

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

†This product is not manufactured or distributed by The Procter & Gamble Company, Vicks®, DayQuil®, NyQuil®, and LiquiCaps® are registered trademarks of the Procter and Gamble Company.

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOW SIGNS OF TAMPERING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

Rev.: 04/2023

Daytime cold & Flu softgel	Nighttime cold & Flu softgel
<b>Drug Facts</b>	<b>Drug Facts</b>
<b>Active ingredients (in each softgel)</b>	<b>Active ingredients (in each softgel)</b>
Acetaminophen 325 mg.....Pain reliever/fever reducer	Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....Cough suppressant	Dextromethorphan HBr 15 mg.....Cough suppressant
Phenylephrine HCl 5 mg.....Nasal decongestant	Doxylamine succinate 6.25 mg.....Antihistamine
<b>Uses</b>	<b>Uses</b>
• temporarily relieves common cold and flu symptoms • cough due to minor throat and bronchial irritation • nasal congestion • headache • minor aches and pains • fever • sore throat	• temporarily relieves common cold and flu symptoms • cough due to minor throat and bronchial irritation • sore throat • headache • minor aches and pains • fever • runny nose and sneezing
<b>Warnings</b>	<b>Warnings</b>
<b>Liver warning:</b> These products contain acetaminophen. Severe liver damage may occur if you take: • more than 4,000 mg of acetaminophen in 24 hours • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this products	<b>Liver warning:</b> These products contain acetaminophen. Severe liver damage may occur if you take: • more than 4,000 mg of acetaminophen in 24 hours • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this products

**DAYTIME NIGHTTIME COLD FLU RELIEF**  
acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24689-152
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24689-152-01	1 in 1 CARTON; Type 0: Not a Combination Product	05/11/2023	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	16 BLISTER PACK	16
Part 2	32 BLISTER PACK	32

**Part 1 of 2****NIGHTTIME COLD FLU RELIEF**

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule

**Product Information**

<b>Item Code (Source)</b>	NDC:24689-157
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<b>Route of Administration</b>	ORAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	



GELATIN (UNII: 2G86QN327L)

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	23mm
<b>Flavor</b>		<b>Imprint Code</b>	AA7
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		1 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 Drug	M012	05/11/2023	

### Part 2 of 2

### DAYTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

### Product Information

<b>Item Code (Source)</b>	NDC:24689-158
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	23mm
<b>Flavor</b>		<b>Imprint Code</b>	AA6
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		32 in 1 CARTON		
1		1 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 Drug	M012	05/11/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/11/2023	

**Labeler - APNAR PHARMA LP (079568229)**

**Establishment**

Name	Address	ID/FEI	Business Operations
APNAR PHARMA LLP		118530917	manufacture(24689-152) , analysis(24689-152)