

# **NITE-TIME COLD/FLU MEDICINE- acetaminophen liquid**

## **AptaPharma Inc.**

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### **Active Ingredients**

#### Drug Facts

Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg   Dextromethorphan HBr 30 mg   Doxylamine Succinate 12.5 mg

### **Purpose**

Purpose

Pain reliever/fever reducer   Cough suppressant   Antihistamine

### **Keep Out Of Reach Of Children**

**Keep out of reach of children.**

### **Uses**

Uses temporarily relieves cold/flu symptoms:

- sore throat
- minor aches and pain
- runny nose and sneezing
- cough due to minor sore throat and bronchial irritation
- headache
- fever

### **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ● more than 4 doses (30 mL each) in 24 hours, which is the maximum daily amount for this product ● with other drugs containing acetaminophen ● 3 or more alcoholic drinks everyday 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.

### **Ask A Doctor**

Ask a doctor before use if you have

- a sodium restricted diet
- liver disease
- glaucoma
- 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 enlarged prostate gland

### **Ask A Doctor Or Pharmacist**

Ask a doctor or pharmacist before use

- if you are taking sedatives or tranquilizers
- if you are taking the blood thinning drug warfarin

### **When Using This Product**

When using this product

- do not use more than directed
- avoid alcoholic drinks
- excitability may occur, especially in children
- marked drowsiness may occur
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### **Stop Use And Ask A Doctor**

Stop use and ask a doctor if

- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash, headache that lasts

### **Pregnant Or Breast-Feeding**

If pregnant or breast-feeding, ask a health professional before use.

### **Overdose Warning**

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

### Directions

- take only as recommended-see Overdose warnings
- Use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours

adults and children 12 years and over

30 mL (2TBSP) every 6 hours

children 4 to under 12 years

ask a doctor

children under 4 years

do not use

- If taking Nite Time at night and Day Time during the day, limit total to 4 doses per 24 hours

## Other Information

### Other information

- each 30 mL dose cup contains:
  - sodium 45 mg
  - store at room temperature

## Inactive Ingredients

Inactive ingredients: citric acid, D and C yellow No. 10, FD and C Green No. 3, FD and C Yellow No. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

## Do Not Use

### 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 sleepy

## Package Label - Night Time Cold & Flu Relief

NDC 76281-501-28

### AP SAFE

**\*COMPARE TO  
the active ingredients in  
VICKS® NYQUIL®**

# Night Time

**Acetaminophen - Pain Reliever/Fever Reducer  
Dextromethorphan HBr - Cough Suppressant  
Doxylamine Succinate - Antihistamine**

**Multi-Symptom  
Cold & Flu Relief**

**Original Flavor**

**12 FL OZ (354 mL)**

**DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN**

Failure to follow these warnings could result in serious consequences

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil®.

**Manufactured by: AptaPharma Inc.,  
1533 Union Ave., Pennsauken, NJ 08110**

**12 OZ**

<b>Drug Facts (continued)</b>	
■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness	
<b>Stop use and ask a doctor if</b> ■ redness or swelling is present ■ symptoms do not get better within 7 days or are accompanied by a fever ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ cough lasts more than 7 days, comes back, or occurs with fever, 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.	
<b>Overdose warning:</b> Taking more than the recommended dose (overdose) may cause liver damage. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
<b>Directions</b> ■ take only as recommended-see Overdose warning ■ Use dose cup or tablespoon (TBS) ■ do not exceed 4 doses per 24 hours ■ If taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours.	
adults & children 12 years and over	30 mL (2 TBS) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use
<b>Other information</b> ■ each 30 mL dose cup contains: sodium 45 mg ■ store at room temperature	
<b>Inactive ingredients</b> citric acid, D&C yellow # 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose	
<b>Questions?</b> Call weekdays 1-877-798-5944	
*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil®. Manufactured by: AptaPharma Inc., 1533 Union Ave., Pennsauken, NJ 08110	

Made in USA  
AP-LR-08 Rev 01

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NDC 76281-501-28

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\*COMPARE TO the active ingredients in VICKS® NYQUIL®

# Night Time

Acetaminophen - Pain Reliever/Fever Reducer  
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**Multi-Symptom  
Cold & Flu Relief**

Original Flavor

12 FL OZ (354 mL)

**DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN**  
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**Drug Facts**

Active ingredients (in each 30 mL dose cup)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine

**Uses** temporarily relieves cold/flu symptoms: ■ sore throat ■ headache  
■ minor aches and pain ■ fever ■ runny nose and sneezing  
■ cough due to minor throat and bronchial irritation

**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses (30 mL each) 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  
**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash  
If a skin reaction occurs, stop use and seek medical help right away.  
**Severe throat warning:** If sore throat is severe, persists for more than two 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. ■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor. ■ 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 sleepy

**Ask a doctor before use if you have** ■ a sodium restricted diet ■ liver disease ■ glaucoma ■ 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 enlarged prostate gland.

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

**When using this product** ■ do not use more than directed ■ avoid alcoholic drinks ■ excitability may occur, especially in children ■ marked drowsiness may occur

**6 OZ**

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN  
Failure to follow these warnings could result in serious consequences

**Drug Facts**  
**Active Ingredients (In each 30 mL dose cap)** Pyropae  
 Acetaminophen 350 mg Pain reliever/fever reducer  
 Dextromethorphan HBr 30 mg Cough suppressant  
 Doxylamine Succinate 12.5 mg Antihistamine

**Uses** Temporarily relieves cold/flu symptoms ■ sore throat  
 ■ headache ■ minor aches and pain ■ fever ■ runny nose and sneezing  
 ■ cough due to minor throat and bronchial irritation

**Warnings** Liver warning: The product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses (30 mL each) 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 the product.

**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.  
**See brief warning:** If sore throat is severe, persists for more than two

AP SAFE®  
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# Night Time

Acetaminophen - Pain Reliever/Fever Reducer  
 Dextromethorphan HBr - Cough Suppressant  
 Doxylamine Succinate - Antihistamine

Multi-Symptom  
 Cold & Flu Relief

Original Flavor

6 FL OZ (177 mL)

**Drug Facts (continued)**  
 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  
 ■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor ■ 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 sleepy

**Ask a doctor before use if you have** ■ a sodium restricted diet ■ liver disease ■ cirrhosis

This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark, Vicks® NYQUIL®.

Manufactured by: ApixPharma Inc., Made in USA  
 1533 Union Ave. AP-18  
 Pennsauken, NJ 08110

EXP. LOT. PEEL HERE

**Drug Facts (continued)**  
 ■ cough that occurs with too much phlegm (mucus)  
 ■ a breathing problem or chronic cough that lasts or recurs with smoking, asthma, chronic bronchitis or emphysema ■ trouble urinating due to enlarged prostate gland.

**Ask a doctor or pharmacist before use** ■ if you are taking sedatives or tranquilizers ■ if you are taking the blood thinning drug warfarin

**When using this product** ■ do not use more than directed ■ avoid alcoholic drinks ■ excitability may occur especially in children ■ marked drowsiness may occur ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness

**Stop use and ask a doctor if** ■ redness or swelling is present ■ symptoms do not get better within 7 days or are accompanied by a fever ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ cough lasts more than 7 days, comes back, or occurs with fever, 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 this and all drugs out of the reach of children.

**Overdose Warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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 recommended—see Overdose warning ■ Use dose cap or tablespoon (TBSF)  
 ■ do not exceed 4 doses per 24 hours ■ If taking Night, Time of night and Day Time during the day, limit total to 4 doses per 24 hours.

adults & children 12 years and over	30 mL (2 TBSF) every 6 hours
children 4 years to under 12 years	ask a doctor
children under 4 years	do not use

**Other information** ■ each 30 mL dose cap contains sodium 45 mg ■ store at room temperature

**Inactive ingredients** Citric acid, D&C Yellow #10, FD&C Green #3, FD&C Yellow #6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

**Questions?** Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-6944

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NITE-TIME COLD/FLU MEDICINE			
acetaminophen liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-501
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCROSE</b> (UNII: C151H8M554)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-501-28	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
2	NDC:76281-501-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/09/2018	

**Labeler** - Aptapharma Inc. (790523323)

**Registrant** - Aptapharma Inc. (790523323)

## Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(76281-501)

Revised: 12/2023

Aptapharma Inc.