

**ACETAFLU NIGHTTIME- acetaminophen, diphenhydramine hcl, phenylephrine hcl powder**  
**Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals**

*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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**Active ingredients (in each packet)**

**Purposes**

Acetaminophen 650 mg.....	Pain reliever/fever reducer
Diphenhydramine hydrochloride 25 mg.....	Antihistamine/cough suppressant
Phenylephrine hydrochloride 10 mg.....	Nasal decongestant

**Uses**

- temporarily relieves these symptoms due to a cold:
- minor aches and pains • minor sore throat pain • headache • nasal and sinus congestion
- runny nose • sneezing • itchy nose or throat • itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

**Warnings**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 packets in 24 hours, which is the maximum daily amount
- 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.

**Do not use** • in a child under 12 years of age • if you are allergic to acetaminophen

- 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 • high blood pressure • thyroid disease • diabetes • glaucoma
- a sodium-restricted diet • trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema, asthma or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema

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

- sedatives or tranquilizers • the blood thinning drug warfarin

**When using this product**

- do not exceed recommended dosage • avoid alcoholic drinks • marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially with children

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- symptoms do not get better or worsen
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough 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 care professional before use.

### **KEEP OUT OF REACH OF CHILDREN**

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

### **Directions**

- do not use more than directed
- take every 4 hours; do not take more than 6 packets in 24 hours unless directed by a doctor

<b>Age</b>	<b>Dose</b>
children under 4 years of age	do not use
children 4 to under 12 years of age	do not use unless directed by a doctor
adults and children 12 years of age and over	one packet

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10 – 15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating.

Do not overheat.

### **Other Information**

- each packet contains: sodium 20 mg
- store at controlled room temperature 20-25°C (68-77°F). Protect from excessive heat and moisture.

### **Inactive ingredients**

sodium citrate, mannitol, aspartame, hydroxypropyl cellulose, citric acid, tween 80, acesulfame potassium, flavors, sodium bicarbonate

### **Product Label**

# Nighttime AcetaFlu

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.  
KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

## Drug Facts

Active Ingredients (In each packet)	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
Diphenhydramine Hydrochloride 25 mg	Antihistamine/cough suppressant
Phenylephrine Hydrochloride 10 mg	Nasal decongestant

### Uses

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - nasal and sinus congestion
  - runny nose
  - sneezing
  - itchy nose or throat
  - itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

### Warnings

- Liver warnings:** This product contains acetaminophen. Severe liver damage may occur if you take more than 6 packets in 24 hours, which is the maximum daily amount.
- 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.
- Do not use:**
  - in a child under 12 years of age
  - if you are allergic to acetaminophen
  - with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
  - with any other product containing diphenhydramine, even one used on the skin
- 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
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema, asthma or chronic bronchitis
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema

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

- sedatives or tranquilizers
- the blood thinning drug warfarin

### When using this product

- do not exceed recommended dosage
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially with children

### Stop use and ask a doctor if

- numbness, tingling, or sleepiness occurs
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of serious condition.

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

### KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

## Drug Facts (continued)

### Directions

- do not use more than directed
- take every 4 hours; do not take more than 6 packets in 24 hours unless directed by a doctor

Age	Dose
children under 12 years of age	do not use
adults (including 12 years of age and over)	one packet

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10 - 15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

### Other information

- each packet contains sodium 20 mg
- store at controlled room temperature 20-25°C (68-77°F). Protect from excessive heat and moisture.

### Inactive ingredients

sodium citrate, mannitol, aspartame, hydroxypropyl cellulose, citric acid, tween 80, acetaminophen potassium, tartraz, sodium bicarbonate

### Questions or Comments?

call 1-800-494-5560 (Mon-Fri 9AM-5PM PST)

### TAMPER EVIDENT INNER UNIT.

DO NOT USE IF SEALED ACETAFLU PACKET IS TORN OR BROKEN.

Distributed by:  
Affordable Quality Pharmaceuticals  
Garden Grove • CA 92641 • USA

NDC 13411-839-06

# AcetaFlu

## Nighttime

### SEVERE COLD & COUGH

ACETAMINOPHEN • PAIN RELIEVER/FEVER REDUCER  
DIPHENHYDRAMINE HCl • ANTIHISTAMINE/COUGH SUPPRESSANT  
PHENYLEPHRINE HCl • NASAL DECONGESTANT

Nasal Congestion • Cough  
Runny Nose • Sneezing  
Body Ache  
Sore Throat Pain  
Headache • Fever



Infused with Ginger,  
Lemongrass & Lemon

6 PACKETS

## AcetaFlu

### SEVERE COLD & COUGH



Batch No.:  
Mfg. Date:  
Exp. Date:

Rev.033020

## ACETAFLU NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13411-839
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 2 g

<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 2 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 2 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13411-839-06	6 in 1 BOX	03/24/2020	
1		2 g in 1 PACKET; 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	03/24/2020	

**Labeler** - Advanced Pharmaceutical Services, Inc. DbA Affordable Quality Pharmaceuticals (187498279)

### Establishment

Name	Address	ID/FEI	Business Operations
S.P.M CORPORATION		555279715	manufacture(13411-839)

Revised: 3/2020

Advanced Pharmaceutical Services, Inc. DbA Affordable Quality Pharmaceuticals