ACETAFLU NIGHTTIME EFFERVESCENT- acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, effervescent

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.

Active ingredients (in each tablet)

Purposes

Acetaminophen 650 mg	Pain reliever/fever reducer
Diphennhydramine 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 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 tablets 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
- trouble urinating due to an enlarged prostate gland 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 the blood thinning drug warfarin

When using this product • do not exceed recommended dosage. avoid alcoholic drinks marked drowsiness may occur.

Alcohol, sedatives and tranquilizes 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 or 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 take more than the the recommended dose
- adults and children 12 years and over: take 1 tablet fully dissolved in 8 oz of water every 4 hours. Do not exceed 6 tablets in 24 hours or as directed by a doctor
- children under 12 years: do not use

Other information

- each tablet contains: sodium 272 mg
- store at room temperature. Avoid excessive heat.

Inactive ingredients

mannitol, aspartame, kollidon 30, citric acid, tween 20, sodium citrate, sodium bicarbonate, sodium carbonate, flavors, polyethylene glycol,

dimethicone

Product Label



ACETAFLU NIGHTTIME EFFERVESCENT

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13411-841
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	650 mg	
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE	10 mg	

Inactive Ingredients				
Ingredient Name	Strength			
MANNITOL (UNII: 3OWL53L36A)				
ASPARTAME (UNII: Z0H242BBR1)				
PO VIDONE K30 (UNII: U725QWY32X)	PO VIDO NE K30 (UNII: U725QWY32X)			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				
POLYSORBATE 20 (UNII: 7T1F30 V5YH)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)				
SODIUM CARBONATE (UNII: 45P3261C7T)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
DIMETHICO NE (UNII: 92RU3N3Y1O)				

Product Characteristics			
Color	white	Score	no score
Shape	ROUND (TABLET)	Size	3mm
Flavor		Imprint Code	
Contains			

1	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13411-841-16	4 in 1 BOX	03/24/2020	
1		4 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	03/24/2020	

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

Establishment			
Name	Address	ID/FEI	Business Operations
S.P.M CORPORATION		555279715	manufacture(13411-841)

Revised: 3/2020

Advanced Pharmaceutical Services, Inc. Dba Affordable Quality Pharmaceuticals